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Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission:	Board of Pharmacy
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

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1140-09-.01	Manufacturer and Wholesaler Licensing
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(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

Department of Health
Division of Health Related Boards

Chapter 1140-01
Introductory Rules

Amendments

Rule 1140-01-.01 Definitions is amended by adding new paragraphs (8), (9), (33), (34), (38) and (39) and renumbering the remaining paragraphs accordingly, so that as amended, the new paragraphs (8), (9), (33), (34), (38), and (39) shall read:

- (8) "Commercially available" means any marketed FDA-approved drug or biologic product not currently listed on any official shortage list recognized by the Board of Pharmacy.
- (9) "Component" means any active ingredient, or any added substance, inactive ingredient, excipient or pharmaceutical ingredient, intended for use in the compounding of a drug product, including those that may not appear on the product label.
- (33) "Sterile product" means any dosage form, drug product, or biological product devoid from all living microorganisms, including but not limited to bacteria and fungus.
- (34) "Sterile manufacturing" means the production, propagation, processing, pooling, or repackaging of sterile products for wholesale or any other form of distribution, not pursuant to a prescription or medical order.
- (38) "USP" means the United States Pharmacopeia.
- (39) "USP standards" means any applicable standard or standards published in the most current version of United States Pharmacopeia National Formulary guidelines, to the extent that such guidelines do not conflict with state law, rules, or Board Policy Statements and as those guidelines may, from time to time, be amended.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301 and 63-10-304.

Rule 1140-01-.02 Violations Constitute Unprofessional Conduct is amended by deleting the language of the rule in its entirety and substituting instead the following language, so that as amended, the rule shall read:

- (1) Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of *T.C.A. § 63-10-305(6)*.

Authority: T.C.A. §§ 63-10-301, 63-10-304 and 63-10-305.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler Licenses is amended by deleting the title in its entirety and substituting instead the following language, so that as amended, the new title shall read:

1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses.

Authority: T.C.A. §§ 63-10-204, 63-10-301 and 63-10-304.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by changing the word "wholesaler" to "wholesaler/distributor" each time it appears in paragraphs (1), (2), and (3) and subparagraph (3)(b) and its parts 1 and 2, so that as amended, the new paragraphs (1), (2), and (3) and subparagraph (3)(b) and its parts 1 and 2, shall read as follows:

- (1) Application for a license to operate as a pharmacy practice site, manufacturer or wholesaler/distributor within the state of Tennessee shall be submitted to the office of the board at least thirty (30) days prior to

the scheduled opening date. No pharmacy practice site, manufacturer or wholesaler/distributor may open within the state of Tennessee until a license has been obtained; and such license will not be issued until an inspection by an authorized representative of the board has been made.

- (2) An application for an existing pharmacy practice site, manufacturer or wholesaler/distributor physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer or wholesaler/distributor changes name, location or ownership.
 - (a) Transactions constituting a change of ownership include, but are not limited to, the following:
 1. A sole proprietor becomes a member of a partnership or corporation, which succeeds him as the new operator;
 2. A partnership dissolves;
 3. One partnership is replaced by another through the removal, addition or substitution of a partner;
 4. Two (2) or more corporations merge and the originally-licensed corporation does not survive; and
 5. Transfers between levels of government.
 - (b) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives; and
 3. Corporate stock transfers or sales, even when a controlling interest.
- (3) No out-of-state pharmacy practice site, manufacturer or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer or wholesaler/distributor obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer or wholesaler/distributor physically located out-of-state the following standards must be met.

(b) Manufacturer or wholesaler/distributor.

1. Submit an application for a license, which shall include the address of the manufacturer or wholesaler/distributor, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license.
2. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler/distributor is physically located. Thereafter, the manufacturer or wholesaler/distributor shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler/distributor is physically located.

Authority: T.C.A. §§ 63-10-204, 63-10-301 and 63-10-304.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by changing the word "board" to "Board of Pharmacy" in part (3)(b)3. As amended, part (3)(b)3 shall read:

3. Comply with the requirements contained in Chapter 1140-09 of the rules of the Board of Pharmacy.

Authority: T.C.A. §§ 63-10-204, 63-10-301 and 63-10-304.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by deleting paragraph (4) in its entirety and substituting the following language, so that as amended, the new paragraph (4) shall read:

- (4) Representatives of a manufacturer or wholesaler/distributor conducting business in the state of Tennessee and who possesses and distributes controlled substances shall obtain a controlled substance registration from the Board of Pharmacy.

Authority: T.C.A. §§ 53-11-301, 53-11-302, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by adding new paragraph (5) and renumbering the remaining paragraphs accordingly, so that as amended, the new paragraph (5) shall read:

- (5) A manufacturer conducting business in the state of Tennessee and who manufactures, prepares, propagates, repackages, or processes sterile drug products or biological products using aseptic processing must register and possess a modifier as a sterile manufacturer with the Board of Pharmacy in accordance with this chapter. This section shall not apply to wholesalers/distributors of sterile products.

Authority: T.C.A. §§ 63-10-204, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-01-.10 Fees is amended by deleting paragraph (3) in its entirety and substituting instead the following language, so that as amended, the new paragraph (3) shall read:

- (3) Each person becoming licensed as a pharmacist shall pay a registration fee of one-hundred twenty-five dollars (\$125.00). Each person licensed as a pharmacist who desires to continue in the practice of pharmacy shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of one-hundred twenty-five dollars (\$125.00). Each person licensed as a pharmacist and who wishes to obtain an inactive license shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of sixty-three dollars (\$63.00).

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-306 and 63-10-308.

Rule 1140-01-.10 Fees is amended by deleting paragraphs (4), (5), (6), (7), (8) and (15) in their entirety and substituting instead the following language, and by adding new paragraph (16), so that as amended, the new paragraphs (4), (5), (6), (7), (8), (15), and (16) shall read:

- (4) Each person becoming registered as a pharmacy technician shall pay a registration fee of seventy-five dollars (\$75.00). Each person who desires to continue to practice as a pharmacy technician shall biennially, on or before the last day of the month that the person's registration shall expire, pay a renewal fee of seventy-five dollars (\$75.00).
- (5) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any establishment or institution where prescription drugs and devices and related materials are kept for the purpose of the compounding and dispensing of medical and prescription orders shall pay a registration fee of three-hundred dollars (\$300.00) biennially. Any new pharmacy practice site to be opened or established, or any change in location, name or ownership of any existing pharmacy practice site, shall before active operation obtain a license from the Board of Pharmacy and shall pay a fee of three-hundred dollars (\$300.00)
- (6) All manufacturers and wholesalers/distributors of prescription drugs and devices and related materials doing business in the state of Tennessee must be licensed by the Board of Pharmacy by paying a registration fee of five-hundred twenty-five dollars (\$525.00), and thereafter a biennial renewal fee of five-hundred twenty-five dollars (\$525.00)
- (7) The fee for the Board of Pharmacy's publication of Pharmacy Drug Laws, Rules and Regulations shall be an amount which covers the cost of publication and shipping, as determined by the Board of Pharmacy.
- (8) The charge for a roster of Tennessee pharmacies, pharmacists and printing of mailing labels of Tennessee pharmacies and pharmacists shall be determined by the administration of the Department of Health.

- (15) Any person who holds a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall pay a renewal fee of one-hundred dollars (\$100.00) biennially from the date of issuance.
- (16) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any other establishment licensed pursuant to this chapter, where sterile products are compounded, manufactured, prepared, propagated, repackaged, processed, stored, or distributed shall pay a registration fee of two-hundred and fifty dollars (\$250.00), and thereafter a biennial renewal fee of two-hundred and fifty dollars (\$250.00).

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-306 and 63-10-308.

Rule 1140-01-.11 Controlled Substance Registration is amended by adding the word "distributor" to the unnumbered introductory paragraph of the rule which shall read:

No licensee may obtain, possess, administer, dispense, distribute, or manufacture any controlled substance in this state, and no representative of a manufacturer or wholesaler/distributor may distribute any controlled substance in this state, without obtaining a controlled substance registration from the board. Application for such registration shall be submitted on a form prescribed by the board, and shall be accompanied by a fee of forty dollars (\$40.00) and thereafter a biennial renewal fee of forty dollars (\$40.00).

Authority: T.C.A. §§ 53-10-303, 63-10-102, 63-10-404, 63-10-504, and 63-10-508.

Rule 1140-01-.13 Standards for Manufacturers and Wholesalers is amended by deleting the title in its entirety and substituting instead the following language, so that as amended, the new title shall read:

1140-01-.13 Standards for Manufacturers and Wholesalers/Distributors.

Authority: T.C.A. §§ 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-01-.13 Standards for Manufacturers and Wholesalers/Distributors is amended by deleting the rule in its entirety and substituting instead the following language, so that as amended, the rule shall read:

No license to operate a new or remodeled manufacturer or wholesaler/distributor location within the state of Tennessee, or an existing manufacturer or wholesaler/distributor location which changes location or ownership, will be issued unless the manufacturer or wholesaler/distributor meets the standards set forth in Chapter 1140-09 of the rules of the Board of Pharmacy.

Authority: T.C.A. §§ 63-10-301, 63-10-304 and 63-10-306.

Chapter 1140-07 Sterile Product Preparation in Pharmacy Practice

Amendments

Rule 1140-07-.03 Physical Requirements is amended by deleting paragraph (1) and its subparagraphs in their entirety and substituting instead the following language, so that as amended, the new paragraph (1) shall read:

- (1) Any facility that compounds sterile products shall comply with applicable USP standards.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-07-.04 Policy and Procedure Manual is amended by deleting paragraph (1) but not its subparagraphs, and also by deleting subparagraph (1)(n) in its entirety, and by substituting instead the following language, so that as amended, the new paragraph (1) and new subparagraph (1)(n) shall read:

- (1) A policy and procedure manual related to sterile product compounding shall be available for inspection at the pharmacy practice site. The manual shall include policies and procedures for sterile compounding pursuant to USP standards, and shall, at a minimum, include:

- (n) public safety relative to harmful sterile products, including the active notification of patients if they may be affected by a product found to have a defect or an out-of-specification result including any recall policy and procedures;

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-07-.04 Policy and Procedure Manual is amended by deleting subparagraph (1)(o) in its entirety and substituting instead the following language, and is further amended by adding subparagraphs (1)(q) and (1)(r) and paragraphs (2) and (3), so that as amended, the new subparagraphs (1)(o), (1)(q) and (1)(r) and the new paragraphs (2) and (3) shall read:

- (o) attire;
 - (q) compliance with all applicable USP standards; and
 - (r) response to adverse events, outbreaks, and other public health threats associated with products compounded, dispensed, manufactured, propagated, distributed, or otherwise processed at the facility, including procedures for the rapid compilation and dissemination of records to appropriate authorities.
- (2) Any licensed facility which engages in sterile compounding shall conduct an annual review of its policy and procedure manual, and shall update its policy and procedure manual as necessary.
 - (3) Failure by any licensee or registrant to comply with its policy and procedure manual, or any part of this rule shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-07-.05 Labeling is amended by deleting subparagraphs (1)(a), (1)(g), and (1)(j) in their entirety and substituting instead the following language, so that as amended, the new subparagraphs (1)(a), (1)(g), and 1(j) shall read:

- (a) patient's name (if for outpatient use) or healthcare entity name;
- (g) expiration date and, when applicable, expiration time, Beyond Use Dating (BUD);
- (j) directions for use (if for outpatient), if applicable.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-07-.07 Attire is amended by deleting paragraph (1) and its subparagraphs in their entirety, by deleting paragraphs (2), (3), (4), and (5) in their entirety, and by substituting instead the following language, so that as amended, the new paragraph (1) shall read:

- (1) All pharmacists, pharmacy interns and pharmacy technicians shall wear applicable outer garments and shall use respiratory precautions as set out in USP 797.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-07-.08 Quality Assurance is amended by adding paragraphs (3), (4), and (5) which shall read:

- (3) All quality assurance programs shall follow applicable USP standards.
- (4) As part of its quality assurance program, any licensed facility which engages in sterile compounding shall perform a gap analysis pursuant to guidelines adopted by the Board of Pharmacy. Any exceptions or serious deficiencies noted in this analysis shall be reported to the Board of Pharmacy.
- (5) Failure by any licensee or registrant to comply with its quality assurance program shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable,

immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Chapter 1140-09
Manufacturers and Wholesalers

Amendments

Chapter 1140-09 Manufacturers and Wholesalers is amended by deleting the chapter title in its entirety and substituting the following language, so that as amended, the new chapter title shall read:

1140-09 Manufacturers and Wholesalers/Distributors

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.01 Manufacturer and Wholesaler Licensing is amended by deleting the title in its entirety and substituting instead the following language, and is further amended by deleting paragraph (1) in its entirety and substituting instead the following language, so that as amended, the new title and new paragraph (1) shall read:

1140-09-.01 Manufacturer and Wholesaler/Distributor Licensing.

- (1) Every manufacturer or wholesaler/distributor, before engaging in the manufacture, sale or distribution of prescription drugs and prescription devices in this state, must be licensed by the Board in accordance with this chapter.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by changing the word "wholesaler" to "wholesaler/distributor" each time it appears in paragraph (1) and in subparagraphs (1)(a), (1)(b), (1)(c), and (1)(e), so that as amended, the new paragraph (1) and subparagraphs (1)(a), (1)(b), (1)(c), and (1)(e) shall read as follows:

- (1) The board shall require the following minimum information from each manufacturer or wholesaler/distributor applying for a license or any renewal of such license:
- (a) The name, full business address, and telephone number of the manufacturer or wholesaler/distributor;
 - (b) All trade or business names used by the manufacturer or wholesaler/distributor;
 - (c) Addresses, telephone numbers, and the names of contact persons for all facilities used by the manufacturer or wholesaler/distributor for storage, handling, and distribution;
 - (e) The name(s) of the owner and/or operator of the manufacturer or wholesaler/distributor, including:

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by deleting the word "and" from part (1)(e)4. and is further amended by deleting the period and substituting a semicolon as well as the word "and" after part (1)(e)5. which shall read:

- 4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
- 5. DEA registration number if applicable; and

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by adding new part (1)(e)6 and by adding new paragraphs (2) and (3) and renumbering the existing paragraph accordingly, so that as amended, the new part

(1)(e)6 and new paragraphs (2) and (3) shall read:

6. The results of a criminal background check for the owner or manager of the facility seeking licensure, submitted directly to the Board of Pharmacy by the vendor identified in the Board of Pharmacy's licensure application materials.
- (2) Applicants seeking to register as manufacturers shall provide the following materials to the Board of Pharmacy:
 - (a) Proof of registration with the Food and Drug Administration as a manufacturer and the most current inspection by that agency, or correspondence or other written proof from the Food and Drug Administration which states that registration with that agency is unnecessary;
 - (b) The name and contact information of the owner, the owner's agent, or another such individual employed at or contracted by the applicant that can be reached at any time by the Board of Pharmacy, the Department of Health or any agents thereof in the event of a potential or actual public health threat related to the sterility or potency of any drug or biologic product manufactured, wholesaled or distributed by the applicant.
 - (3) Applicants seeking to register as sterile manufacturers shall provide the following materials to the Board of Pharmacy:
 - (a) Upon request by the Board of Pharmacy or the executive director, a list of sterile products currently being manufactured, wholesaled and distributed;
 - (b) The name and contact information for any laboratory, corporation, or other organization that may perform sterility and potency testing, or similar procedures for the purposes of quality assurance on any drug or biologic product produced by the applicant;

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by deleting newly-renumbered paragraph (4) in its entirety and substituting instead the following language, so that as amended, newly-renumbered paragraph (4) shall read:

- (4) Changes in any information in paragraphs (1), (2), or (3) of this rule shall be submitted in writing to the Board of Pharmacy immediately.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.03 Minimum Qualifications is amended by changing the word "wholesaler" to "wholesaler/distributor" in paragraph (1), so that as amended, paragraph (1) shall read as follows:

- (1) The board shall consider, at a minimum, the following factors in reviewing an application for a license as a manufacturer or wholesaler/distributor:

Authority: T.C.A. §§ 63-10-404 and 63-10-504.

Rule 1140-09-.04 Personnel is amended by changing the word "wholesaler" to "wholesaler/distributor" so that as amended, the rule shall read as follows:

The board shall require that personnel employed by a manufacturer or wholesaler/distributor have appropriate education and/or experience to assume positions of responsibility for compliance with board requirements.

Authority: T.C.A. §§ 63-10-404 and 63-10-504.

Rule 1140-09-.05 Minimum Requirements for Operation is amended by deleting the title in its entirety and substituting instead the following language, so that as amended, the new title shall read:

1140-09-.05 Minimum Requirements for General Operation.

Rule 1140-09-.05 Minimum Requirements for General Operation is amended by deleting the title paragraph, subparagraphs (5)(c) and (6)(a) but not its parts, paragraph (7) and part (7)(b)2 as well as subparagraphs (7)(c) and (7)(d) in their entirety and substituting instead the following language, and is further amended by deleting paragraphs (8) and (9), subparagraphs (9)(a) and (9)(b), and paragraph (10) in their entirety and substituting instead the following language, so that as amended, the new title paragraph, paragraphs, subparagraphs and part shall read:

The following shall be the minimum requirements for the storage and handling of prescription drugs and prescription devices and for the establishment and maintenance of prescription drug and prescription device distribution records by manufacturers and wholesalers/distributors:

- (5) (c) If the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, then the prescription drug or prescription device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the prescription drug or prescription device meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, the manufacturer or wholesaler/distributor shall consider, among other things, the conditions under which the prescription drug or prescription device has been held, stored or shipped before or during return and the condition of the prescription drug or device or related material and its container, carton, or labeling, as a result of storage or shipping.
- (6) (a) Manufacturers and wholesalers/distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription devices. These records shall include the following information:
 - (7) Written policies and procedures. Manufacturers and wholesalers/distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs and prescription devices; including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Manufacturers and wholesalers/distributors shall include in written policies and procedures the following:
 - (b)
 - 2. Any voluntary action by the manufacturer or wholesaler/distributor to remove defective or potentially defective prescription drugs and prescription devices from the market; or
 - (c) A procedure to ensure that manufacturers and wholesalers/distributors prepare for, protect against, and respond to any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
 - (d) A procedure to ensure that any outdated prescription drugs and prescription devices shall be segregated from other prescription drugs and prescription devices and either returned to the manufacturer or wholesaler/distributor or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs and prescription devices. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs and prescription devices.
- (8) Responsible persons. Manufacturers and wholesalers/distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of distribution, storage, and handling, including a description of such persons' duties and a summary of such persons' qualifications.
- (9) Compliance with federal, state, and local law. Manufacturers and wholesalers/distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
 - (a) Manufacturers and wholesalers/distributors shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect premises and delivery vehicles, and to

audit records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

- (b) Manufacturers and wholesalers/distributors that handle controlled substances shall register with the board and with the United States Drug Enforcement Administration (DEA) and shall comply with applicable state, local and DEA regulations.
- (10) Salvaging and reprocessing. Manufacturers and wholesalers/distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to salvaging or reprocessing of prescription drugs and prescription devices.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

New Rule

Chapter 1140-01
Introductory Rules

Rule 1140-01-.12
Sterile Product Registration

New Rule: 1140-01-.12 New Table of Contents.

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1140-01-.14	Standards for Manufacturers and Wholesalers/Distributors
1140-01-.15	Prescription Drugs Dispensed by Health Departments

- (1) No licensee may compound, manufacture, prepare, propagate, or process any sterile product to be dispensed, sold, traded, or otherwise distributed in or from this state without first obtaining a sterile compounding modifier registration from the Board of Pharmacy.
- (2) A registration modifier to compound and dispense sterile products into or from this state may be suspended by the Board of Pharmacy, upon information that the registrant has:
 - (a) Knowingly furnished false or fraudulent material information in any application filed before the Board of Pharmacy; or
 - (b) Been convicted of a felony under any state or federal law relating to drugs or to the practice of pharmacy; or
 - (c) Had any of its licenses, permits, or registrations granted by the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Department of Health and Human Services (DHHS), or any other federal agency or subdivision thereof, suspended, revoked, or voluntarily surrendered; or
 - (d) Been enjoined from operation by the court of any state or a federal court; or

- (e) Been identified by the Commissioner of Health or the Commissioner's designee, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), or an investigator of the Board of Pharmacy as a source of adulterated, misbranded, or otherwise unsafe sterile products which have been, or pose an imminent risk of being dispensed, sold, traded, or otherwise distributed.
- (3) An order of suspension issued by the Board of Pharmacy may contain additional directives or requirements necessary to protect public health, safety and welfare, including but not limited to:
- (a) The quarantine or disposal of any sterile product compounded, manufactured, prepared, propagated or processed at the facility.
 - (b) The initiation of a recall of any sterile product compounded, manufactured, prepared, propagated or processed at the facility where such products or any label, container, packaging, or dosage form associated with such products may be adulterated, misbranded, contaminated, or otherwise unsafe.
 - (c) An order of suspension issued by the Board of Pharmacy may contain exceptions or allowances necessary to protect individual patients or the public health.
- (4) Any order of suspension issued by the Board of Pharmacy pursuant to this chapter shall follow the procedures required by the Uniform Administrative Procedures Act, including those procedures required by T.C.A. § 4-5-320(d) where appropriate.

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-305 and 63-10-306.

New Rule

Chapter 1140-07
Sterile Product Preparation in Pharmacy Practice

1140-07-.02
Standards

New Rule: 1140-07-.02 New Table of Contents.

1140-07-.01	Applicability
1140-07-.02	Standards
1140-07-.03	Personnel
1140-07-.04	Physical Requirements
1140-07-.05	Policy and Procedure Manual
1140-07-.06	Labeling
1140-07-.07	Hazardous Products
1140-07-.08	Attire
1140-07-.09	Quality Assurance

- (1) All sterile products shall be prepared in compliance with applicable USP standards for pharmaceutical compounding.
- (2) The Board of Pharmacy, upon a showing of good cause and in the best interest of the public health, safety and welfare, may waive the requirements of any applicable portion of USP standards.
 - (a) All waiver requests submitted pursuant to this part shall be submitted in writing.
 - (b) The Board of Pharmacy may authorize the Executive Director to exercise some, or all, of its waiver authority under this part.
- (3) Noncompliance by a licensee with applicable standards and guidelines, or any other violation of the provisions of this rule shall be considered unprofessional conduct within the meaning of T.C.A. 63-10-305 and a violation of a duly promulgated rule of the Board of Pharmacy.

- (4) Any licensed pharmacy which compounds sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of high risk or batch sterile products, as defined by USP standards, compounded and dispensed during the previous quarterly period and any other information as required by USP standards.
- (a) Quarterly reports submitted pursuant to this paragraph shall be submitted by the 15th day of the month following the end of each calendar quarter.
 - (b) In any calendar year where any one of the above dates fall on a weekend or official state holiday, all quarterly reports due on that date shall be submitted on the following business day.
 - (c) The format for reports submitted pursuant to this paragraph shall be determined by the Board of Pharmacy through policy and made available to the public on the Board of Pharmacy's website.
- (5) Any licensed pharmacy which compounds and dispenses sterile products shall provide at a minimum upon request of the Board of Pharmacy the following information for any sterile drug product compounded, dispensed, traded, sold, or otherwise distributed:
- (a) name, strength, and dosage form;
 - (b) quantity compounded, dispensed, traded, sold, or otherwise distributed during the preceding quarterly period;
 - (c) all components and an accurate statement of the weight or measure of each component;
 - (d) the beyond-use date;
 - (e) storage requirements;
 - (f) labels and labeling with appropriate beyond-use date and instructions for storage and use.
- (6) Any licensed pharmacy which compounds and dispenses sterile products must ensure that the following information is on file at the practice site and readily accessible for sterile products:
- (a) documentation of the name and strength of all drug products compounded over the past two (2) years;
 - (b) the sources and lot numbers of the components used in those drug products;
 - (c) the total number of dosage units compounded over the past two (2) years;
 - (d) the name of the person who prepared the drug product;
 - (e) the name of the pharmacist who approved the drug product;
 - (f) the name of the practitioner or the name of the patient or healthcare entity who received the compounded drug product;
 - (g) the results of any sampling, testing or other quantitative evaluation conducted for the purposes of quality control for any sterile compounded products, as defined by chapter 1140-01, compounded over the past two (2) years.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

New Rule

Chapter 1140-09
Manufacturers and Wholesalers/Distributors

1140-09-.06
Minimum Requirements for Sterile Product Operation.

New Rule: 1140-09-.06 New Table of Contents.

1140-09-.01	Manufacturer and Wholesaler/Distributor Licensing
1140-09-.02	Minimum Information Required
1140-09-.03	Minimum Qualifications
1140-09-.04	Personnel
1140-09-.05	Minimum Requirements for General Operation
1140-09-.06	Minimum Requirements for Sterile Product Operation

- (1) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter that also holds an active sterile compounding registration from the Board of Pharmacy and that holds a license or registration from the Federal Food and Drug Administration, shall comply with all applicable federal laws, regulations, and guidelines including, but not limited to:
 - (a) FDA Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs 21 CFR 210;
 - (b) FDA Current Good Manufacturing Practice for Finished Pharmaceuticals 21 CFR 211;
 - (c) DEA regulations relating to controlled substances 21 CFR 1300-99.
- (2) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy and who does not hold a license or registration from the federal Food and Drug Administration shall comply with all applicable USP standards.
- (3) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy shall comply with all other applicable Board of Pharmacy rules and all other applicable laws of this State.
- (4) The Board of Pharmacy may waive any applicable USP standards upon a showing by the applicant that good cause exists and that a waiver would better promote public health, safety, and welfare.

Authority: T.C.A. §§ 63-10-404 and 63-10-504.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Charles E. (Buddy) Stephens, D.Ph.	X				
Jason Kizer, D.Ph.	X				
Nina Smothers, D.Ph.				X	
Joyce McDaniel	X				
Will Bunch, D.Ph.	X				
Kevin K. Eidson, Pharm. D.	X				
R. Michael Dickenson, D.Ph.	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Pharmacy (board/commission/ other authority) on 07/07/2014 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 05/12/14 (mm/dd/yy)

Rulemaking Hearing(s) Conducted on: (add more dates). 07/07/14 (mm/dd/yy)

Date: 7/8/14

Signature: [Handwritten Signature]

Name of Officer: Stefan Cange

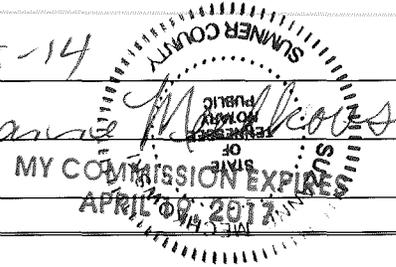
Assistant General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: 7-8-14

Notary Public Signature: [Handwritten Signature]

My commission expires on: APRIL 04 2017



All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

[Handwritten Signature]

Robert E. Cooper, Jr.
Attorney General and Reporter

7-11-14
Date

Department of State Use Only

Filed with the Department of State on: 7/11/14

Effective on: 10/9/14

*Tre Hargett by
Nancy Padgett RDA*
Tre Hargett
Secretary of State

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SECRETARY OF STATE

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Dennis Roberts of Baptist East Hospital in Memphis submitted the following comments via email:

"As far as tracking lot #s from automated dispensing cabinets, that will be virtually impossible. If the cabinet has heparin 5000 unit vials stocked, they will all be in one drawer and there could be multiple lot numbers. There is no way to know which vial or lot # the nurse picks from that drawer. Omnicell has no ability to add this capability to their system. Once the lot numbers are imbedded in the bar codes, bedside med verification could capture the lot numbers but there is no way of knowing how far off that technology is. Until technology is available, there is no way to be compliant with this rule."

"There are several other issues regarding the proposed rules but this one is the most troubling. I hope the Board will take into consideration hospitals like Baptist East. I have 109 automated dispensing cabinets and that is just on site. We also have cabinets in other campus locations. It appears the Board's objective is to track lot numbers to patients for all medications dispensed. What about areas that use floor stock and the medications are charged and restocked manually?"

"I appreciate what the Board is trying to do in the interest of patient safety but it will not help patients if the Board enacts rules that cannot be complied with."

Nancy Granger, D.Ph., Inpatient Pharmacy Operations Manager, Fort Sanders Regional Medical Center along with Chris Norris Pharm D., Pharmacy Director, a pharmacist at Fort Sanders Regional Medical Center submitted a letter via email to the Board of Pharmacy addressing concerns over the rule amendments. They admit that changes in sterile compounding rules are needed; however, they are concerned that the rules as written will require too much time with recordkeeping and other paperwork, stating that their hospital would require hundreds a day to be logged which would require additional staff and delay patients from receiving necessary compounding medicine timely. They also point out that rule 1140-07-.02(5) and (6) seem to be stating the same thing with (6) requiring stricter compliance measures. They fear that keeping the records required would be too voluminous, and that it may require computer records which would be costly. Additionally, they have concerns that labeling each product and notating each patient that receives them would disturb the hospital's current distribution process. Ultimately, they do not feel like this paragraph was written with hospitals in mind. Lastly, they request, that if the Board adopts these amendments, language can be included to exempt hospitals from the labeling requirement. They summarize the letter by stating, "[t]o fully implement the 2014 Chapter 1140-7 Sterile Product Preparation rules will jeopardize our ability to stock compounded sterile products on nursing units where they can be readily available for critically ill patients. The rules will also delay getting immediate use preparations from the pharmacy to the patient due to time consuming recordkeeping."

Jeanne Ezell, M.S., FASHP, Director of Pharmacy and Residency Program, at Blount Memorial Hospital also submitted comments to the Board via email. Blount Memorial services outpatients who receive sterile products, and as such, Ms. Ezell would like the Board to address an exemption for such services as the status of the patients makes sterile product administration harder to track. She also request that the Board clarify if a hospital is required to report sterile products administered when a nursing home requests that same from the hospital. Ms. Ezell also expresses the same concerns mentioned above by representatives of Fort Sanders Medical Center with regards to rule 1140-07-.02(5) and (6). Regarding 1140-07-.03, Ms. Ezell questions whether a technician would be excluded from purchasing and storing, etc. any materials used in sterile compounding. She states that Blount Memorial uses pharmacy technicians to order materials and to monitor and document observation tests as using a pharmacist for these tasks would be a waste of time. She further states that "quality assurance" and "quality control" need to be defined, because in the rules, the elements of the two seem to be similar. Lastly, Ms. Ezell does agree with requiring Work Practice Guidelines for Personnel Dealing with Cytotoxic Drugs and ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Substances, but she questions whether pharmacists mixing chemo or chemo prep competencies need to re-read these materials annually.

The Board did not directly address any of the written comments during the hearing.

The first public comments at the rulemaking hearing came from Jim Hinkle, a pharmacist at the University of Tennessee Medical Center. He expressed the University's full support of the goals of the rules, to promote public safety. He mentioned that there may be some confusion as there seems to be no distinction in the rules between sterile and non-sterile components. The University hospital feels that sterile compounding using non-sterile components should carry greater restrictions than sterile compounding where all components are sterile to begin with.

Richard Green, Director of Radiopharmacy Practice with Cardinal Health, addressed the Board with concerns over nuclear pharmacies that compound nearly all of their products, but do not engage in high-risk sterile compounding. He went on to say that the unique practice would be financially pressed to comply with the gap analysis presented in rule 1140-07-.08. Additionally, Dr. Green expressed similar concerns about the breadth of record-keeping requirements contained in the proposed rules.

The Board later considered comments and decided to amend rule 1140-07-.02(4) to specify that persons compounding or dispensing high risk or batch sterile products must comply with tracking requirements. The Executive Director of the Board and legal staff further clarified that many of the record-keeping concerns (e.g., the mistaken belief that patient names would have to be written on the label of every dose of compounded medication used in a hospital emergency room; the recording and/or assignment of lot numbers for individual dosage units of medication, rather than the maintenance of a lot numbers only for the bulk components used to compound those dosage units) were not reflected in the actual language of the rules themselves.

Dr. Brenda Warren with Accredo Health commented on several provisions within the rules. Her first comment centered on rule 1140-07-.01. She suggested that the Board may want to specify that product requirements for this rule are applicable for those drugs in or coming into Tennessee. She also suggested that the Board replace "USP standards" in rule 1140-07-.02(1) with "Board of Pharmacy", so as to not limit the Board to the current USP restrictions. Dr. Warren suggested that the Board model a form for reporting similar to the Massachusetts form. Dr. Warren also commented on and suggested a revision to rule 1140-07-.03(1)(f) to include the words "as needed" after twenty four (24) hour a day basis, while also questioning whether the Board meant to add an annual CE requirement or just simply require training. Dr. Warren also commented on labeling stating that it was hard to find the pharmacists that actually signed off on the sterile product. Lastly, she asked the Board if all of these requirements align with USP 797.

Mark Sullivan, a pharmacist with Vanderbilt University Medical Center, also commented on the rules, first asking the Board whether the term "commercially available" was meant to be used in context with hospitals, which often compound commercially available drug products for "in-house" use on patients. Dr. Sullivan also asked if hospitals could be exempt from these requirements for outpatients as well as inpatients (current law exempts hospital inpatients from many requirements of the Board's compounding rules). Dr. Sullivan raised the issue of capital costs to comply with the record-keeping requirements in the rules. The hospital would need to invest money in computer systems and other mechanisms in order to keep the required records. Lastly, Dr. Sullivan encouraged the Board to look at future rulemaking that would place tougher restrictions and requirements on companies or labs who conduct quality assurance testing and similar evaluations on compounded products.

Mark Binkley, pharmacist and owner of Health and Wellness Compounding Pharmacies, spoke in support of the rules as written. He noted that the focus of these rules was to promote public health and safety and that it would require careful examinations on the number of sterile products that were prescribed and dispensed. He also noted that his pharmacy currently has a tracking program that is very easy to use and that operates by scanning a bar code. He does not think that the rules would require unnecessary or burdensome recordkeeping for independent pharmacies like his own.

Baeteena Black, a representative of the Tennessee Pharmacy Association which also submitted written comments, orally reiterated some key points of the Association's letter. Dr. Black mentioned that several references were made to outpatients and asked the Board if they intended exemptions for hospital outpatients similar to those already present for inpatients. She added that TPA feels that quarterly reporting by every compounder for every sterile product produced, whether low, medium or high risk, would be of little value to the Board. She also addressed the labeling requirements and noted that complying with these requirements would be very difficult for an institutional pharmacy, specifically the patient name requirement for labels. As pointed out above, the rules actually allow an institution to put the institution's name on the label instead of an individual patient. This permissive language would allow the hospital to put an institutional name on a vial of medication to be used in the emergency room.

Regarding rule 1140-07-.02, the TPA urges the Board to come into compliance with USP 797, stating that batch versus individual requirements would create some unintended barriers to these rules. She went on to express support for the Board in the purpose of its rulemaking.

Bill Greene, a pharmacist with St. Jude, also commented on the rules. He also mirrored the comments above regarding inpatients and outpatients, but felt that this issue was less important than drawing regulatory distinctions between products which are low risk, medium risk, and high risk. He commended the Board for its quality assurance measures. He also noted that technology used at St. Jude does not currently allow for lots numbers to be recorded by bar code, that they must be hand-entered.

Chuck Ashley with Methodist Medical Center of Oak Ridge submitted comments in tune with those submitted by other hospitals. Dr. Nina Smothers, a Board member who was not present at the hearing, spoke with attorney Stefan Cange by phone the day before the hearing and expressed similar concerns. Mr. Cange discussed Dr. Smothers' concerns before the Board during the hearing.

The Board asked whether drugs could be tracked by bar code.

Bruce Warren with St. Jude answered by explaining that computers track products by bar code with a picture taken under the hood, to have a bar code track the individual drug and the patient that received that drug, those type of records must be entered manually.

The Board also discussed the difference between outpatients and inpatients. It considered adding a definition of "outpatient" to the rules. Dr. Reginald Dilliard, Executive Director of the Board of Pharmacy, suggested basing future definitions of inpatient and outpatient on the definitions used by the Center for Medicare and Medicaid Services (CMS).

Dr. Black, with the Tennessee Pharmacists Association, again spoke regarding this issue stating that the CMS definition creates problems because this definition separates outpatients for Medicare billing purposes, not for purposes of labeling sterile products. The Board did not vote to incorporate the new definition. The Board did resolve during the hearing to implement a policy statement interpreting the terms "inpatient" and "outpatient" as used in the rules at its July 30 and 31 meeting. Board staff will solicit stakeholder input for this policy statement between July 7 and the July 30, 31 meeting.

Dr. Hinkle and Dr. Greene again commented on the issue with lot numbers. Both parties believed that it would be difficult for institutional facilities to maintain records of lot numbers if those numbers were assigned to individual compounded doses of medication. Dr. Buddy Stephens, Board member, emphasized the importance of keeping records of lot numbers for reporting purposes. Dr. Stephens noted that high-volume non-institutional pharmacies keep extensive records of the drugs they dispense, and did not understand why a large institution would not be able to similarly comply.

Dr. Mark Binkley commented that the assignment of lot numbers to individual doses is more stringent than USP standards, but noted that the tracking of lot numbers was crucial for quality assurance and public safety. Dr. Binkley again argued that such recordkeeping should not present a problem for any institution because it is necessary to ensure public health. Bruce Warren with St. Jude once again commented on the paucity of tracking software and methods, concerned that if the rules become effective, St. Jude's will not be able to comply with them.

The Board addressed this concern by stating that it still has the power to grant temporary waivers to ease institutions into compliance with reporting requirements. Additionally, as mentioned earlier, many institutions believed that the rules would have required the assignment of lot numbers to individual doses of medication. For a hospital that compounds thousands of doses of sterile products each day, such a requirement could be overly burdensome. However, as written and adopted by the Board, the rules only require hospitals to maintain records of lot numbers for "components" of compounded products. Therefore, lot numbers for individual doses do not need to be recorded or assigned, only the lot numbers of the products which are used to make those dosage units need to be recorded.

Ultimately, the Board unanimously accepted the rules in their entirety, with one amendment to rule 1140-07-.02(4), which now shall read: "[a]ny licensed pharmacy which compounds sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of high risk or batch sterile products, as defined by USP standards, compounded and dispensed during the previous quarterly period and any other information as required by USP standards." The

Board voted to add the words "high risk or batch" and "as defined by USP standards." This amendment would exempt medium and low-risk sterile compounded products from the quarterly reporting requirements. Coupled with the clarification of rule language at this hearing with respect to lot numbers (the rules do not require lot numbers to be assigned to individual compounded doses of medication) and labeling (the rules do not require an institution to place a patient name on a label for medications used in the emergency room, that are administered during an outpatient surgical procedure, or under similar circumstances) this amendment greatly reduces the record-keeping requirements for stakeholders. It should also serve to streamline government operations by reducing the amount of paperwork that needs to be processed by Board staff.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

REGULATORY FLEXIBILITY ANALYSIS

(1) The extent to which the rule or rule may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

The amended rules do not overlap, duplicate, or conflict with other federal, state, and local government rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

The amended rules exhibit clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

Compliance and reporting requirements were intended to be as unobtrusive as possible, while still protecting public safety. The proposed rules also allow the Board of Pharmacy to grant exemptions from compliance and reporting requirements upon a showing of good cause.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

The schedules and deadlines for compliance and reporting are objective and occur at regular intervals. The Board will also conduct outreach and provide education to stakeholders.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

The reporting requirements are the same for both small and large businesses. The requirements are well-defined.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

The proposed rules do not set any performance standards, but do establish design and operational standards. The proposed rules also allow the Board of Pharmacy to grant exemptions from these standards.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

The amended rules create no entry barriers or other effects that would stifle legitimate entrepreneurial activity, curb innovation, or increase costs for legitimate businesses. Many of the requirements imposed by these proposed rules have already been adopted by a plurality of other states. Many of the proposed requirements are equal to, or less stringent than, equivalent federal statutes and rules. Most of the impacted stakeholders already comply with these other state and federal standards.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Tennessee Board of Pharmacy

Rulemaking hearing date: TBD

1. Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:

Some pharmacies, hospitals, drug/medical device manufacturers, drug/medical device manufacturers/distributors, and other entities tangentially involved in the pharmaceutical and medical device industries may have to bear significant compliance costs.

2. Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:

In keeping with the requirements imposed by Public Chapter 266, additional reporting requirements for compounding pharmacies must be satisfied. These reports can be prepared by clerical or administrative staff, but will likely be generated automatically by software.

The proposed rules would also require some additional record-keeping requirements, which could be performed by clerical or administrative staff, but again will likely be facilitated or completed through the use of software.

3. Statement of the probable effect on impacted small businesses and consumers:

Many small businesses in the drug and device industry already comply with the standards proposed by this rule and will not bear any additional costs due to its implementation. These nationally-recognized standards have been implemented in dozens of states and largely equivalent to federal standards, so small businesses which routinely operate outside Tennessee or deal with federal authorities on a regular basis may derive some benefit from these rules, as they will not have any additional compliance costs. Unsophisticated, poorly managed small businesses, or those which purposely operate in legal grey-areas, will be negatively impacted by the proposed rules.

The proposed rules are designed to protect the public and ensure the stability of drug supplies. Both of these would have a positive effect on consumers.

4. Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:

The proposed rules would allow the Board of Pharmacy to grant exemptions from the more burdensome requirements upon a showing of good cause. The Department of Health, in cooperation with the Board, is in the process of designing a form to facilitate the application for and consideration of exemptions to the proposed rules. There are no less burdensome, intrusive, or costly alternative methods which provide the same level of protection to the public. Due to the exigent circumstances surrounding the fungal meningitis outbreak and subsequent outbreaks of infections associated with unsafe compounded products, the proposed rules represent the best and only way to protect the public as well as the legitimacy of the pharmacy compounding industry.

5. Comparison of the proposed rule with any federal or state counterparts:

Federal: Currently, there is no exact language for these proposed rules in the federal laws. Similar federal rules imposed on drug manufacturers registered with FDA, known as "Good manufacturing Practices" are substantially more stringent than the proposed rules. Recent federal legislation (Drug Quality and Security Act of 2013) imposes equivalent standards on

"outsourcing facilities," which are entities which compound drugs pursuant to sales orders, or other non-prescription orders (the drugs are not designated for a specific patient).

State: Most other states have adopted standards which mirror, or are largely equivalent to, the proposed rules. A tiny minority of states have standards which are less stringent than those contained in the proposed rules.

6. Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

Small businesses, upon a showing of good cause, can apply for an exemption from certain provisions of the proposed rules. Such exemptions will allow these businesses to continue operating and providing critically needed drugs to those in need. A complete exemption from the proposed rules for small businesses would defeat the purpose of the proposed rule and places the public at risk.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The proposed rules would make substantial additions to the current pharmacy rules, especially with regard to the compounding and distribution of sterile products. Several new definitions must be added to Tenn. R. Comp. & Reg. 1140-01-.01 in order to comply with current law. No definitions in that section will be modified or deleted.

The proposed rules also increase fees for licensees, and require any licensee engaged in sterile compounding or that handles or distributes sterile products to purchase an additional registration from the Board of Pharmacy. The proposed rules would create a new section 1140-01-.12 which deals with these sterile product registrations.

The proposed rules also renumber current sections 1140-01-.12, 1140-01-.13, and 1140-01-.14 as 1140-01-.13, 1140-01-.14, and 1140-01-.15 accordingly.

The proposed rules would extensively modify Tenn. R. Comp. & Reg. 1140-07. New section 1140-07-.02 "Standards" would be created, and would contain requirements mandating that licensees who compound sterile products comply with sterility guidelines adopted by the Board and new reporting requirements imposed by state law. Sections 1140-07-.03, 1140-07-.04, 1140-07-.05, 1140-07.07 and 1140-07.08 are amended to require compliance with Board sterility guidelines, rather than the specific and inadequate provisions currently effective. Proposed modifications to Sections 1140-07-.04 would require an expansion of the areas covered in licensees' Policy and Procedure manual, and would further require compliance with the Policy and Procedure manual.

Proposed modifications to Section 1140-07-.08 would also require licensees to perform a gap analysis in between inspections by Board investigators, and would require licensees to report exceptions or deficiencies uncovered by those analyses to the Board.

Proposed modifications to Tenn. R. Comp. & Reg. 1140-09 would require sterile products manufacturers to provide the following materials to the Board of Pharmacy: upon request by the Board of Pharmacy or the executive director, a list of sterile products currently being manufactured, wholesaled and distributed and the name and contact information for any laboratory, corporation, or other organization that may perform sterility and potency testing, or similar procedures for the purposes of quality assurance on any drug or biologic product produced by the applicant. Section 1140-09-.02 would be modified to require that owners or managers of such facilities submit to a criminal background check. The title of Section 1140-09-.05 is amended to include the word "General" so that it now reads "Minimum Requirements for General Operation." New section 1140-09-.06 would be created, titled "Minimum Requirements for Sterile Product Operation," which would require manufacturers or wholesaler/distributors to comply with Board guidelines for the manufacture or distribution of sterile drug products.

Subsequent to the July 7 rulemaking hearing, the Board voted to amend the proposed changes to Section 1140-07-.02(4), drastically reducing reporting requirements for affected stakeholders. Prior to the hearing, the proposed rules would have required quarterly reporting of all products compounded by licensees. As amended, the proposed rules will only require quarterly reporting of sterile compounded products produced in batch lots not pursuant to a patient-specific prescription or medical order, they will also require the reporting of all high-risk sterile products (whether batch-made or patient-specific). This change would exempt patient-specific low and medium-risk compounded products from the quarterly reporting requirements (low- and medium-risk products are compounded much more often than high-risk ones).

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

None.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

These proposed rules will have a significant impact on pharmacies, hospitals, drug manufacturers, drug

wholesaler/distributors, and other business entities engaged in the fabrication, distribution, processing, or related aspects of the pharmaceutical and healthcare industry.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

None.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

The proposed rules should not result in an increase or decrease in state and local government revenues and expenditures.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Stefan Cange, Assistant General Counsel, Department of Health

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Stefan Cange, Assistant General Counsel, Department of Health

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

665 Mainstream Drive, Nashville, Tennessee 37243, (615)741-1611, Stefan.Cange@tn.gov.

- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

**.RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-01
INTRODUCTORY RULES**

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Licenses

1140-01-.01 DEFINITIONS.

- (1) "ACPE" means the Accreditation Council for Pharmaceutical Education.
- (2) "Alternate or alternative infusion pharmacy practice site" means a pharmacy practice site where parenteral, enteral or respiratory therapies, and ancillary supplies, medications and equipment are provided to patients in a non-institutional setting.
- (3) "Accreditation Council for Pharmacy Education (ACPE)" means the national organization for accreditation of professional degree programs in pharmacy and for accreditation of providers of continuing pharmacy education.
- (4) "~~Blood~~" means ~~whole blood collected from a single donor and processed either for transfusion or further manufacturing.~~
- (5) "Blood fraction/component" means that part of blood separated by physical or mechanical means.
- (6) "Centralized Prescription Processing" is the filling or refilling of a lawful prescription order written by the patient's authorized prescriber by one (1) pharmacy licensed by the State of Tennessee at the request of another pharmacy licensed by the State of Tennessee for the delivery of the prescription drugs to the patient or patient's agent.
- (7) "Certified pharmacy technician" means an individual who is certified by a national or state agency that offers a certification program that is recognized by the board.
- (8) "Commercially available" means any marketed FDA-approved drug or biologic product not currently listed on any official shortage list recognized by the Board of Pharmacy.
- (9) "Component" means any active ingredient, or any added substance, inactive ingredient, excipient or pharmaceutical ingredient, intended for use in the compounding of a drug product, including those that may not appear on the product label.

(Rule 1140-01-.01, continued)

- (10)(8) "Consultant pharmacist" means a pharmacist retained on a routine basis to consult with organizations, institutional facilities or patients in areas that pertain to the practice of pharmacy.
- (11)(9) "Contact hour" means any hour of completed continuing pharmaceutical education programming which is:
- (a) accredited by ACPE (including, but not limited to, live programs, independent study courses, home correspondence courses, and audio or video cassettes); or
 - (b) approved by the board (including, but not limited to, attendance at state, district, or local pharmacy association meetings).
- (12)(40) "Continuing education unit" means ten (10) hours of participation in an ACPE approved or board-approved continuing pharmaceutical education program under responsible sponsorship, capable direction, and qualified instruction.
- (13)(41) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the prescription drug.
- (14)(42) "Electronic medical or prescription order" means a medical or prescription order which is transmitted by computer technology other than by electronic image transmission.
- (15)(43) "Facsimile (FAX) medical or prescription order" means a medical or prescription order which is transmitted by an electronic image transmission.
- (16)(44) "Foreign pharmacy graduate" means a person whose undergraduate pharmacy degree was conferred by any college or school of pharmacy not accredited by the ACPE but which is listed in the World Health Organization World Directory of Colleges and Schools of Pharmacy, or otherwise approved by the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification program as established by the National Association of Boards of Pharmacy.
- (17)(45) "Hazardous product" means any substance that may be cytotoxic, genotoxic, oncogenic, mutagenic, teratogenic, or otherwise pose a potential health hazard.
- (18)(46) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, and where patients spend a majority of their time within the facility, including but not limited to a(n):
- (a) adult care facility;
 - (b) assisted living facility;
 - (c) correctional facility;
 - (d) developmental disability center;
 - (e) hospital;
 - (f) inpatient psychiatric center;
 - (g) intermediate care facility for the mentally retarded;
 - (h) mental health facility;
 - (i) nursing facility;
 - (j) personal care home;
 - (k) rehabilitation center;
 - (l) residential drug or alcohol treatment center;
 - (m) rest home;
 - (n) retirement center;
 - (o) sub-acute care facility; and

(Rule 1140-01-.01, continued)

(p) university health center.

~~(19)~~~~(47)~~ "Institutional pharmacy practice site" means a pharmacy practice site serving patients within an institutional facility.

~~(20)~~~~(48)~~ "Medication order" means a prescription order for any prescription drug or device or related material issued by an authorized prescriber to authorized healthcare personnel in an institutional facility or institutional pharmacy practice site.

~~(21)~~~~(49)~~ "National Association of Boards of Pharmacy (NABP)" means the professional organization that represents the individual state boards of pharmacy.

~~(22)~~~~(20)~~ "Nuclear pharmacy practice site" means a pharmacy practice site providing radiopharmaceutical services.

~~(23)~~~~(24)~~ "Patient counseling" means communication by the pharmacist of information to the patient or caregiver in order to improve therapeutic outcome.

~~(24)~~~~(22)~~ "Pharmaceutical care" is the responsible provision of drug therapy through, among other things, pharmacists identifying potential and actual drug-related problems and resolving and preventing drug-related problems, for the purpose of achieving definite outcomes that improve a patient's quality of life. The outcomes include but are not limited to cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process and the preventing of a disease or symptomatology.

~~(25)~~~~(23)~~ "Pharmacy internship" is a period of practical pharmacy experience under the direct supervision of a licensed pharmacist and pursuant to the rules of the board.

~~(26)~~~~(24)~~ "Pharmacy practice site" means any place within this state where prescription drugs or prescription devices are dispensed and where pharmaceutical care is provided, and any place outside of the state where prescription drugs or prescription devices are dispensed and pharmaceutical care is provided to persons residing in this state.

~~(27)~~~~(25)~~ "Preceptor" means an individual who is currently licensed as a pharmacist and who meets the qualifications of a preceptor under the rules of the board and participates in the education of pharmacy interns.

~~(28)~~~~(26)~~ "Prescription department" means the area of a pharmacy practice site in which prescription drugs and devices and related materials are stocked and medical and prescription orders are compounded and dispensed.

~~(29)~~~~(27)~~ "Quality assurance" means a system for identifying problems in patient care that are resolved via administrative, clinical, or educational actions to ensure that final products and outcomes meet applicable specifications.

~~(30)~~~~(28)~~ "Radiopharmaceutical service" means, but is not limited to:

- (a) the compounding, dispensing, labeling, and delivering of radiopharmaceuticals;
- (b) the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;
- (c) the proper and safe storage and distribution of radiopharmaceuticals;
- (d) the maintenance of radiopharmaceutical quality assurance;

(Rule 1140-01-.01, continued)

- (e) the responsibility for advising, where necessary or where regulated, of the diagnostic and therapeutic value, hazards, and use of radiopharmaceuticals; and
 - (f) the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy practice site.
- ~~(31)~~(29) "Reciprocity" means to issue a license to an applicant who furnishes satisfactory proof of licensing by examination in another state or territory pursuant to the rules of the board.
- ~~(32)~~(30) "Shall" means that compliance is mandatory.
- (33) "Sterile product" means any dosage form, drug product, or biological product devoid from all living microorganisms, including but not limited to bacteria and fungus.
- (34) "Sterile manufacturing" means the production, propagation, processing, pooling, or repackaging of sterile products for wholesale or any other form of distribution, not pursuant to a prescription or medical order.
- ~~(35)~~(34) "Third party pharmacy program" means any system of providing for the reimbursement of medical or prescription orders and/or pharmaceutical care services under a contractual arrangement or agreement between a provider of such services and the third party program administrator who is not the consumer of those services.
- ~~(36)~~(32) "Third party pharmacy program administrator" means, but is not limited to, insurance companies, managed care organizations, health maintenance organizations, preferred provider organizations, pharmacy benefit managers, and pharmacy services administrative organizations.
- ~~(37)~~(33) "Unit dose packaging" means that packaging which is designed to hold a quantity of a drug product intended for administration as a single dose.
- ~~(38)~~(34) "USP" means the United States Pharmacopeia.
- (39) "USP standards" means any applicable standard or standards published in the most current version of United States Pharmacopeia National Formulary guidelines, to the extent that such guidelines do not conflict with state law, rules, or Board Policy Statements and as those guidelines may, from time to time, be amended.

Authority: T.C.A. §§ 63-10-101, 63-10-102, 6-10-404(5), (6), (14), (22), (26), (28), and (29), 63-10-304, 63-10-304(b)(1), 63-10-504(b)(1), and Chapter 966 of the Public Acts of 2008 §1. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010.

1140-01-.02 VIOLATIONS CONSTITUTE UNPROFESSIONAL CONDUCT.

- ~~(1) Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-505(6).~~

(Rule 1140-01-.01, continued)

- (1) Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-504(b)(1), and 63-10-505(6).
Administrative History: Original rule certified June 7, 1974. Amendment filed August 14, 1974; effective September 13, 1974. Repeal filed January 11, 1977; effective February 10, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.03 APPLICATION FOR A PHARMACIST LICENSE.

- (1) An applicant for a license to engage in the practice of pharmacy shall submit the following to the Board office at time of application:
 - (a) A completed application on a form approved by the Board;
 - (b) Application and registration fees established in rule 1140-01-.10; and
 - (c) The result of a criminal background check, which the applicant shall pay for and cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials.
 - (d) Any application submitted which lacks required information or reflects a failure to meet any of the requirements for licensure will be returned to the applicant with written notification of the information that is lacking or the reason(s) the application does not meet the requirements for licensure and will be held in "pending" status until satisfactorily completed within a reasonable period of time, not to exceed sixty (60) days from date of written notification.
- (2) For the purpose of T.C.A. § 63-10-506(d), a "recognized" college or school of pharmacy is a college or school of pharmacy which meets the minimum standards of the ACPE and appears in the ACPE "Annual Directory of Accredited Professional Programs of Colleges and Schools of Pharmacy."
- (3) No applicant shall be eligible for a license if the applicant has engaged in conduct or suffers a condition which would constitute grounds for revocation or suspension of a license under T.C.A. § 63-10-505, unless the applicant can show cause why a license should be issued.
- (4) No license shall be issued to a reciprocal applicant from a state which denies reciprocal privileges to a pharmacist currently licensed and in good standing in Tennessee.
- (5) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.
- (6) An applicant initially licensed in another state and who wishes to obtain a Tennessee license may, in the discretion of the board, transfer to Tennessee the applicant's score on NAPLEX taken in another state. Provided, however, if the applicant has been licensed for twelve (12) or more months in another state, then the applicant shall apply for a license in Tennessee by reciprocity. No license shall be issued to a score transfer applicant from a state which denies score transfer privileges to a pharmacist currently licensed and in good standing in Tennessee.

(Rule 1140-01-.03, continued)

Authority: T.C.A. §§ 63-10-101, 63-10-102(a), 63-1-116, 63-10-202, 63-10-304, 63-10-306, 63-10-404(2), (13), (17), and (26), 63-10-404(2), (13), (17), and (26), 63-10-504(b)(1), 63-10-506, and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed January 4, 2012; effective April 3, 2012.

1140-01-.04 PHARMACY INTERNSHIP.

- (1) An applicant for an initial pharmacist license by examination must show, on affidavit forms prescribed by the board, that the applicant has acquired a minimum of one thousand five hundred (1,500) hours of pharmacy internship (practical pharmacy experience) under the instruction of a pharmacist in good standing, subject to all of the following conditions.
 - (a) The one thousand five hundred (1,500) hours must be acquired after enrollment in a recognized college or school of pharmacy; one thousand one hundred (1,100) of these hours may be acquired in pharmacy programs or demonstration projects structured by the college or school of pharmacy.
 - (b) Pharmacy internship may be acquired in another state, provided that the preceptor's qualifications are certified by the appropriate authorities of such state.
 - (c) Four hundred (400) of these hours may be acquired in non-traditional pharmacy internship programs which have received prior approval of the board.
 - (d) Foreign pharmacy graduates shall complete five hundred (500) hours of pharmacy internship in Tennessee within a period of six (6) consecutive months.

Authority: T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-404(29), and 63-10-504(b)(1). **Administrative History:** Original rule filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10, 1977. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.05 LICENSING EXAMINATIONS.

- (1) An applicant for an initial license to engage in the practice of pharmacy in the State of Tennessee shall take the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Jurisprudence Examination (MPJE®) and the NABP North American Pharmacy Licensing Examination (NAPLEX®), which shall be administered on the dates scheduled by the NABP. An applicant shall also meet the minimum acceptable passing scores on the NAPLEX® and MPJE® as established and nationally accepted.
- (2) An applicant to obtain a pharmacy license by reciprocity shall successfully complete the MPJE®.
- (3) In addition to completing the requirements in paragraph (1) of this rule, a pharmacy foreign graduate shall successfully complete the foreign pharmacy equivalency examination, the Test of Spoken English (TSE®) examination and any other requirements established by the NABP.
- (4) Any applicant who fails either the NAPLEX® or MPJE® may retake the examinations at any of the next examination dates scheduled by the NABP. If an applicant fails the NAPLEX® or MPJE® three (3) consecutive times, then the Board may require that applicant to take review courses prior to any following reexamination.

(Rule 1140-01-.05, continued)

Authority: T.C.A. §§ 63-10-304 and 63-10-306. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.

1140-01-.06 SUMMARY SUSPENSION OF LICENSE.

Pursuant to T.C.A. § 4-5-320, if the board finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action.

Authority: T.C.A. §§ 4-5-320, 63-10-101, 63-10-102, 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-505. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 15, 1989; effective December 30, 1989. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.07 INACTIVE LICENSES AND LICENSE REINSTATEMENT.

- (1) A pharmacist may apply for an inactive license by:
 - (a) Completing the biennial license renewal application form; and
 - (b) Paying the biennial renewal fee for an inactive license.
- (2) A pharmacist maintaining an active license to practice pharmacy in another state or jurisdiction is ineligible for inactive license status in Tennessee.
- (3) A pharmacist seeking active status for an inactive, delinquent, suspended or revoked license must fulfill the following minimum requirements.
 - (a) If the license has been inactive, delinquent, suspended or revoked for less than one (1) year, the pharmacist shall:
 1. Provide written notice to the board requesting an active license;
 2. Satisfy all past due continuing pharmaceutical education as required by the board; and
 3. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked.
 - (b) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than five (5) consecutive years, the pharmacist shall:
 1. Provide written notice to the board requesting an active license;
 2. Satisfy all past due continuing pharmaceutical education as required by the board;
 3. Successfully complete the jurisprudence examination;
 4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and

(Rule 1140-01-.07, continued)

5. Complete a period of pharmacy internship in Tennessee as follows.
 - (i) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than three (3) consecutive years, one hundred sixty (160) hours within ninety (90) consecutive days.
 - (ii) If the license has been inactive, delinquent, suspended or revoked for more than three (3) consecutive years but not more than five (5) consecutive years, three hundred twenty (320) hours within one hundred eighty (180) consecutive days.
- (c) If the license has been inactive, delinquent, suspended or revoked for more than five (5) consecutive years, the pharmacist shall:
 1. Provide written notice to the board requesting an active license;
 2. Satisfy all past due continuing pharmaceutical education as required by the board;
 3. Successfully complete the NAPLEX and jurisprudence examinations;
 4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and
 5. Complete a period of pharmacy internship of three hundred twenty (320) hours within one hundred eighty (180) consecutive days.
- (d) Fulfill any other requirements which may be contained in any order of the board suspending or revoking the applicant's license.
- (e) The board shall consider a written notice requesting reinstatement of an inactive, delinquent, suspended or revoked license within ninety (90) days of the notice being received by the director.
- (f) The board shall consider a waiver upon request.

Authority: T.C.A. §§ 63-10-101, 63-10-102, 63-10-210, 63-10-404(17), and 63-10-504(b)(1).
Administrative History: Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10, 1977. Amendment filed April 11, 1979; effective July 30, 1979. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.08 APPLICATION FOR PHARMACY PRACTICE SITE, MANUFACTURER AND WHOLESALE/DISTRIBUTOR LICENSES.

- (1) Application for a license to operate as a pharmacy practice site, manufacturer or wholesaler/distributor within the state of Tennessee shall be submitted to the office of the board at least thirty (30) days prior to the scheduled opening date. No pharmacy practice site, manufacturer or wholesaler/distributor may open within the state of Tennessee until a license has been obtained; and such license will not be issued until an inspection by an authorized representative of the board has been made.

(Rule 1140-01-.08, continued)

- (2) An application for an existing pharmacy practice site, manufacturer or wholesaler/distributor physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer or wholesaler/distributor changes name, location or ownership.
 - (a) Transactions constituting a change of ownership include, but are not limited to, the following:
 1. A sole proprietor becomes a member of a partnership or corporation, which succeeds him as the new operator;
 2. A partnership dissolves;
 3. One partnership is replaced by another through the removal, addition or substitution of a partner;
 4. Two (2) or more corporations merge and the originally-licensed corporation does not survive; and
 5. Transfers between levels of government.
 - (b) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives; and
 3. Corporate stock transfers or sales, even when a controlling interest.
- (3) No out-of-state pharmacy practice site, manufacturer or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer or wholesaler/distributor obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer or wholesaler/distributor physically located out-of-state the following standards must be met.
 - (a) Pharmacy practice site.
 1. Submit an application for a license, which shall include the address of the pharmacy practice site, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation and names of all pharmacists who practice at the site, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license, including names of pharmacists practicing at the site.
 2. Comply with all statutorily authorized directions and requests for information from the board.
 3. Maintain at all times a current permit, license or registration to conduct the pharmacy practice site in compliance with the laws of the state in which the site is physically located.

(Rule 1140-01-.08, continued)

4. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Thereafter, the pharmacy practice site shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the site is physically located.
 5. Maintain records of prescription orders dispensed to persons residing in Tennessee.
 6. All records of prescription orders prepared and dispensed to persons residing in Tennessee shall be readily retrievable from other records.
 7. During regular hours of operation, but not less than six (6) days per week nor for a minimum of forty (40) hours per week provide access to a pharmacist by a toll-free telephone service. A toll-free number shall be placed on the label affixed to the dispensing container for each prescription dispensed to a person residing in Tennessee.
 8. Designate a pharmacist in charge who shall be responsible for compliance with the provisions in this section, and who shall hold a current Tennessee pharmacist license.
 9. All out-of-state pharmacy practice sites shall comply with the requirements for patient counseling, patient profiling, drug regimen review and pharmaceutical care as set forth at 1140-03-.01.
- (b) Manufacturer or wholesaler/distributor.
1. Submit an application for a license, which shall include the address of the manufacturer or wholesaler/distributor, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license.
 2. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler/distributor is physically located. Thereafter, the manufacturer or wholesaler/distributor shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler/distributor is physically located.
 3. Comply with the requirements contained in Chapter 1140-09 of the rules of the Board of Pharmacy.
- (4) Representatives of a manufacturer or wholesaler/distributor conducting business in the state of Tennessee and who possesses and distributes controlled substances shall obtain a controlled substance registration from the Board of Pharmacy.
- (5) A manufacturer conducting business in the state of Tennessee and who manufactures, prepares, propagates, repackages, or processes sterile drug products or biological products using aseptic processing must register and possess a modifier as a sterile manufacturer with the Board of Pharmacy in accordance with this chapter. This section shall not apply to wholesalers/distributors of sterile products.

(Rule 1140-01-.08, continued)

~~(6)~~(5) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.

~~(7)~~(6) In determining whether to grant a license under this rule, the board shall require from the applicant proof satisfactory to the board that the:

- (a) Applicant is of good moral character, or, if the applicant is a partnership or corporation, that the managing officers are of good moral character; and
- (b) That the applicant is equipped as to land, buildings and equipment necessary to conduct the business for which the application has been submitted.

Authority: T.C.A. §§ 53-11-301, 53-14-104, 53-14-106, 53-14-107, 56-1-302(b)(1)(2), 63-10-101, 63-10-102(a), 63-10-203, 63-10-204, 63-10-210, 63-10-404(18), (28), and (37), 63-10-504(b)(1), § 63-10-504(b)(2), and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed September 30, 1985; effective October 30, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Amendment filed August 25, 1989; effective October 9, 1989. Amendment filed October 30, 1991; effective December 14, 1991. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.09 RENEWAL OF LICENSES.

- (1) All licenses and certificates of registration granted by the board shall be for a two (2) year period beginning on the date the license is initially granted. All licenses and certificates of registration shall be renewed on or before the last day of the two (2) year license cycle.
- (2) A pharmacist or pharmacy technician serving in the uniformed services of the United States shall not be required to pay license or registration renewal fees during the period of active duty and the pharmacist shall not be required to complete continuing pharmacy education requirements during the period of active duty.

Authority: T.C.A. §§ 53-11-301, 53-11-302, 56-1-302(b)(1)(2), 63-10-102(a), 63-10-404(17), 63-10-504(1) and (2), 63-10-304(b)(1) and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed April 12, 1990; effective July 29, 1990. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed December 23, 2009; effective March 23, 2010.

1140-01-.10 FEES.

- (1) An applicant for examination for a license as a pharmacist shall pay a fee of fifty dollars (\$50.00) plus cost of the examination and materials.
- (2) An applicant for a reciprocal license or NAPLEX score transfer shall pay a fee of three hundred dollars (\$300.00).
- (3) Each person becoming licensed as a pharmacist shall pay a registration fee of one-hundred twenty-five dollars (\$125.00) ~~ninety-six dollars (\$96.00)~~. Each person licensed as a pharmacist who desires to continue in the practice of pharmacy shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of one-hundred twenty-five dollars (\$125.00) ~~ninety-six dollars (\$96.00)~~. Each person licensed as a pharmacist and who wishes to obtain an inactive license shall biennially, on or before the last

(Rule 1140-01-.10, continued)

- day of the month that the person's license shall expire, pay a renewal fee of sixty-three dollars (\$63.00), ~~forty-eight dollars (\$48.00)~~.
- (4) Each person becoming registered as a pharmacy technician shall pay a registration fee of seventy-five dollars (\$75.00), ~~fifty dollars (\$50.00)~~. Each person who desires to continue to practice as a pharmacy technician shall biennially, on or before the last day of the month that the person's registration shall expire, pay a renewal fee of seventy-five dollars (\$75.00), ~~fifty dollars (\$50.00)~~.
 - (5) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any establishment or institution where prescription drugs and devices and related materials are kept for the purpose of the compounding and dispensing of medical and prescription orders shall pay a registration fee of three-hundred dollars (\$300.00), ~~one-hundred sixty-eight dollars (\$168.00)~~ biennially. Any new pharmacy practice site to be opened or established, or any change in location, name or ownership of any existing pharmacy practice site, shall before active operation obtain a license from the Board of Pharmacy and shall pay a fee of three-hundred dollars (\$300.00), ~~one-hundred sixty-eight dollars (\$168.00)~~.
 - (6) All manufacturers and wholesalers/distributors of prescription drugs and devices and related materials doing business in the state of Tennessee must be licensed by the Board of Pharmacy by paying a registration fee of five-hundred twenty-five dollars (\$525.00), ~~four hundred eight dollars (\$408.00)~~, and thereafter a biennial renewal fee of five-hundred twenty-five dollars (\$525.00), ~~four hundred eight dollars (\$408.00)~~.
 - (7) The fee for the Board of Pharmacy's publication of Pharmacy Drug Laws, Rules and Regulations shall be an amount which covers the cost of publication and shipping, as determined by the Board of Pharmacy. The fee for the board's publication of Pharmacy-Drug Laws, Rules and Regulations shall be ten dollars (\$10.00).
 - (8) The charge for a roster of Tennessee pharmacies, pharmacists and printing of mailing labels of Tennessee pharmacies and pharmacists shall be determined by the administration of the Department of Health, Commerce and Insurance.
 - (9) The fee for certification of license examination grades shall be twenty five dollars (\$25.00).
 - (10) The fee for a duplicate or revised pharmacist license wall certificate shall be twenty five dollars (\$25.00).
 - (11) If any person fails to renew a license, such license may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars (\$10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.
 - (12) If any person fails to renew a license or registration certificate, such license or registration certificate may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars (\$10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.
 - (13) A penalty of fifty dollars (\$50.00) may, in the discretion of the board, attach to each failure of a licensee or registration certificate holder to provide any required notice to the director as may be required by the rules of the board.

(Rule 1140-01-.10, continued)

- (14) Any licensee who wishes to modify the terms or conditions of a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall file those modifications with a non-refundable fee of five dollars (\$5.00).
- (15) Any person who holds a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall pay a renewal fee of one-hundred dollars (\$100.00)~~sixty dollars (\$60.00)~~ biennially from the date of issuance.
- (16) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any other establishment licensed pursuant to this chapter, where sterile products are compounded, manufactured, prepared, propagated, repackaged, processed, stored, or distributed shall pay a registration fee of two-hundred and fifty dollars (\$250.00), and thereafter a biennial renewal fee of two-hundred and fifty dollars (\$250.00).

Authority: T.C.A. §§ 4-5-202, 63-10-102(a), 63-10-216, 63-10-404(17), 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed December 15, 1977; effective January 16, 1978. Amendment filed September 26, 1978; effective December 29, 1978. Repeal and new rule file February 7, 1983; effective March 9, 1983. Amendment filed May 23, 1986; effective August 12, 1986. Amendment filed January 26, 1987; effective April 29, 1987. Amendment filed October 1, 1987; effective January 27, 1988. Amendment filed November 18, 1989; effective February 28, 1989. Amendment filed October 18, 1990; effective January 29, 1991. Amendment filed May 3, 1991; effective August 28, 1991. Amendment filed December 22, 1992; effective March 31, 1993. Amendment filed June 25, 1993; effective September 28, 1993. Amendment filed October 19, 1996; effective February 28, 1996. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.

1140-01-.11 CONTROLLED SUBSTANCE REGISTRATION.

No licensee may obtain, possess, administer, dispense, distribute, or manufacture any controlled substance in this state, and no representative of a manufacturer or wholesaler/distributor may distribute any controlled substance in this state, without obtaining a controlled substance registration from the board. Application for such registration shall be submitted on a form prescribed by the board, and shall be accompanied by a fee of forty dollars (\$40.00) and thereafter a biennial renewal fee of forty dollars (\$40.00).

Authority: T.C.A. §§ 53-10-303, 63-10-102(a), 63-10-404(6), 63-10-504(b)(1), 63-10-504(b)(1) and (2), and 63-10-508. **Administrative History:** Original rule filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.12 STERILE PRODUCT REGISTRATION

- (1) No licensee may compound, manufacture, prepare, propagate, or process any sterile product to be dispensed, sold, traded, or otherwise distributed in or from this state without first obtaining a sterile compounding modifier registration from the Board of Pharmacy,
- (2) A registration modifier to compound and dispense sterile products into or from this state may be suspended by the Board of Pharmacy, upon information that the registrant has:
- (a) Knowingly furnished false or fraudulent material information in any application filed before the Board of Pharmacy; or

(Rule 1140-01-.12, continued)

- (b) Been convicted of a felony under any state or federal law relating to drugs or to the practice of pharmacy; or
 - (c) Had any of its licenses, permits, or registrations granted by the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Department of Health and Human Services (DHHS), or any other federal agency or subdivision thereof, suspended, revoked, or voluntarily surrendered; or
 - (d) Been enjoined from operation by the court of any state or a federal court; or
 - (e) Been identified by the Commissioner of Health or the Commissioner's designee, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), or an investigator of the Board of Pharmacy as a source of adulterated, misbranded, or otherwise unsafe sterile products which have been, or pose an imminent risk of being dispensed, sold, traded, or otherwise distributed.
- (3) An order of suspension issued by the Board of Pharmacy may contain additional directives or requirements necessary to protect public health, safety and welfare, including but not limited to:
- (a) The quarantine or disposal of any sterile product compounded, manufactured, prepared, propagated or processed at the facility.
 - (b) The initiation of a recall of any sterile product compounded, manufactured, prepared, propagated or processed at the facility where such products or any label, container, packaging, or dosage form associated with such products may be adulterated, misbranded, contaminated, or otherwise unsafe.
 - (c) An order of suspension issued by the Board of Pharmacy may contain exceptions or allowances necessary to protect individual patients or the public health.
- (4) Any order of suspension issued by the Board of Pharmacy pursuant to this chapter shall follow the procedures required by the Uniform Administrative Procedures Act, including those procedures required by T.C.A. § 4-5-320(d) where appropriate.

~~1140-01-.13~~ ~~1140-01-.12~~ **STANDARDS FOR PHARMACIES AND PRESCRIPTION DEPARTMENT SECURITY.**

A license to operate a new or remodeled pharmacy practice site, or an existing pharmacy practice site which changes location or ownership, will not be issued unless the pharmacy practice site meets the following standards.

- (1) The pharmacy practice site and equipment therein shall be maintained in a clean, sanitary, orderly and well-lighted condition, and all persons working in the pharmacy practice site shall be required to keep themselves and their apparel in a clean and sanitary condition.
- (2) All new or relocated pharmacies opening after July 1, 1998 shall provide a consultation area which offers sufficient privacy to the patient before a license will be issued. All existing pharmacies shall be in compliance with this requirement on or before January 1, 2000.

(Rule 1140-01-.12, continued)

- (3) The prescription department at the pharmacy practice site shall meet the following standards.
- (a) The department shall have necessary counters and storage space.
 - (b) The department shall have a representative stock of prescription drugs and devices and related materials sufficient to compound and dispense medical and prescription orders as indicated by experience.
 - (c) The department shall have the apparatus and equipment needed to compound and dispense medical and prescription orders properly.
 - (d) The department shall occupy a space of not less than one hundred eighty (180) square feet.
 - (e) The department shall have hot and cold running water and immediate area refrigeration.
 - (f) The department shall have a physical barrier sufficient to protect against unauthorized entry and pilferage of prescription drugs and devices and related materials.
 - (g) Keys or other access devices to the physical barriers shall be subject to the following standards.
 - 1. Only pharmacists practicing at the pharmacy and pharmacists authorized by the pharmacist in charge shall be in possession of any keys or other access devices.
 - 2. The pharmacist in charge shall place a key or other access device in a sealed envelope bearing the signature of the pharmacist in charge affixed across the seal and placed in a safe or vault in a secured place outside of the department. The key or access device may be used to allow emergency entrance to the department.
 - (h) Access to the department is restricted to pharmacists, pharmacy interns and pharmacy technicians who are practicing at the pharmacy. Other persons designated by the pharmacist in charge may be allowed access but only during hours that a pharmacist is on duty.
 - (i) Notwithstanding any rule or regulation to the contrary, a pharmacy which was established before June 6, 1945, and which serves food, and which has continuously had a soda fountain, may allow a customer to go through the pharmacy area to the restroom, and not be required to have a gate or door to separate the pharmacy from the restroom or other parts of the establishment.
- (4) All licenses and certificates of registration for a pharmacy practice site shall at all times be conspicuously displayed at the practice site.
- (5) If a pharmacy practice site is located in a mercantile establishment (such as a discount store, grocery store, department store, or other similar establishment), then such pharmacy practice site shall be:
- (a) open for business during the same hours as the mercantile establishment, unless the pharmacy practice site is capable of being closed-off by physical barrier from floor to ceiling; and
 - (b) under the supervision of a pharmacist at all times; except as provided in rule 1140-03-.07.

(Rule 1140-01-.12, continued)

- (6) The pharmacist shall not at any time be denied access to the prescription department of a pharmacy practice site located in a mercantile establishment; provided, however, that entry of the pharmacist at times when the pharmacy is closed to the public may be subject to reasonable and prudent conditions.
- (7) A pharmacy practice site where prescription drugs and devices and related materials are received, stored, compounded and dispensed shall not be opened for business or any other reason unless a licensed pharmacist is present. Furthermore, no medical or prescription order shall be dispensed except during the presence and under the direct supervision of a pharmacist.
- (8) Nothing in this rule applies to a pharmacy practice site or prescription department operating in an institutional facility.
- (9) In cases of practical difficulty or undue hardship, the board may permit exceptions to the standards specified in this rule.

Authority: T.C.A. §§ 63-10-404(28), 63-10-504(b)(1), and 63-10-504(b)(1) and (2). **Administrative History:** Original rule filed May 11, 1998; effective July 25, 1998.

~~1140-01-.14~~ ~~1140-01-.13~~ **STANDARDS FOR MANUFACTURERS AND WHOLESALERS/DISTRIBUTORS.**

No license to operate a new or remodeled manufacturer or wholesaler/distributor location within the state of Tennessee, or an existing manufacturer or wholesaler/distributor location which changes location or ownership, will be issued unless the manufacturer or wholesaler/distributor meets the standards set forth in Chapter 1140-09 of the rules of the Board of Pharmacy.

Authority: T.C.A. §§ 63-10-404(18) and (37), and 63-10-504(b)(1). **Administrative History:** Original rule filed May 11, 1998; effective July 25, 1998.

~~1140-01-.15~~ ~~1140-01-.14~~ **PRESCRIPTION DRUGS DISPENSED BY HEALTH DEPARTMENTS.**

For purposes of T.C.A. § 63-10-405, the following drugs are hereby approved as not subject to abuse:

- (1) Tuberculosis Control Agents:
 - (a) Capreomycin Injection
 - (b) Cycloserine Capsules
 - (c) Ethambutol Tablets
 - (d) Ethionamide Tablets
 - (e) Isoniazid Tablets
 - (f) Para-Aminosalicylate Tablets
 - (g) Pyrazinamide Tablets
 - (h) Rifampin Capsules
 - (i) Streptomycin Injection
 - (j) Tuberculin Skin Test (Mantoux only)
 - (k) Rifampin/Isoniazid
 - (l) Ofloxacin
 - (m) Rifampin-isoniazid-pyrazinamide
- (2) Venereal Disease Control Agents:
 - (a) Ampicillin Capsules
 - (b) Doxycycline Capsules

(Rule 1140-01-.14, continued)

- (c) Erythromycin Tablets
 - (d) Penicillin
 - 1. Benzathine Penicillin G Injection
 - 2. Procaine Penicillin G Injection
 - (e) Probenecid Tablets
 - (f) Spectinomycin Injection
 - (g) Tetracycline Capsules
 - (h) Ceftriaxone
 - (i) Ciprofloxacin
 - (j) Lidocaine Injection
 - (k) Azithromycin
 - (l) Acyclovir Tablets, Ointments
 - (m) Trichloroacetic Acid
 - (n) Salicylic Acid
 - (o) Podophyllin/Salicylic Acid
 - (p) Aldara (Imiquimod)
- (3) Biologicals/Immunizations:
- (a) Antiserums
 - (b) Antitoxins
 - (c) Immune Serum Globulin
 - (d) Toxoids
 - (e) Vaccines
 - (f) Antigens
- (4) Reproductive Health Agents:
- (a) Metronidazole Tablets
 - (b) Oral Contraceptives
 - (c) Podophyllin
 - (d) Prenatal Vitamins
 - (e) Triple Sulfa Vaginal Cream/Tabs
 - (f) Vaginal Antifungal Cream/Tabs
 - 1. Clotrimazole
 - 2. Miconazole
 - 3. Nystatin
 - 4. Terconazole (Terazole)
 - (g) Amino-Cerv
 - (h) Nitrofurantoin
 - (i) Ibuprofen, 600 mg Tablets
 - (j) Metronidazole (vaginal jell)
 - (k) Fluconazole Tablets
 - (l) Clindamycin Vaginal Cream
 - (m) Premarin Tablets (for use in estrogen trials for the evaluation of atypical cells in certain inflammatory atrophic pap smears)
 - (n) Medroxyprogesterone Acetate Injectable (Depo Provera®)
 - (o) Norelgestromin/ethinyl estradiol transdermal system (Ortho Evra®)
 - (p) Etonogestrel/ethinyl estradiol vaginal ring (Nuvaring®)
- (5) Child Health Agents:

(Rule 1140-01-.14, continued)

- (a) Fluoride Tablets and Drops
 - (b) Lindane Cream, Lotion, Shampoo
 - (c) Mebendazole Tablets
 - (d) Pyrantel Pamoate Liquid
 - (e) Sulfadiazine Tablets
 - (f) Trimethoprim and Sulfamethoxazole
 - (g) Permethrin
 - (h) Crothamiton
 - (i) Nystatin Oral Suspension
 - (j) Nystatin Triamcinolone Cream
 - (k) Ibuprofen, Suspension Liquid
- (6) Emergency Agents:
- (a) Aminophylline Injection
 - (b) Benztropine Injection
 - (c) Diphenhydramine Injection
 - (d) Epinephrine Injection
 - (e) Glucagon Injection
 - (f) Hydralazine Injection
 - (g) Hydrocortisone Sodium Succinate
 - (h) Insulin, Regular
 - (i) Intravenous Fluids
 - (j) Oxygen
 - (k) Phenylephrine Injection
 - (l) Sodium Bicarbonate Injection
 - (m) Atropine Injection
 - (n) Nitroglycerin Sublingual Tablets
 - (o) Dexamethasone Injection
 - (p) Norepinephrine
- (7) Antihypertensive Agents:
- (a) Methyldopa
 - (b) Reserpine
 - (c) Hydrochlorothiazide
 - (d) Hydralazine
 - (e) Propranolol
 - (f) Potassium Supplements
 - (g) Nicotine Patches

Authority: T.C.A. §§ 63-10-404(14), 63-10-205, 63-10-304, 63-10-304(b)(1), 63-10-405, 63-10-504(b), 63-10-504(b)(1), and 63-10-504(b)(2). **Administrative History:** Original rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010.

(Rule 1140-7-.06, continued)

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-7
STERILE PRODUCT PREPARATION IN PHARMACY PRACTICE**

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1140-7-.01 APPLICABILITY.

The provisions of this Chapter shall apply to all pharmacy practice sites and pharmacists, pharmacy interns, pharmacy technicians and supportive personnel involved in the compounding and dispensing of sterile products.

Authority: T.C.A. § 63-10-404(4),(11),(26),(28),(29),(30), § 63-10-504(b)(1),(2). *Administrative History:* Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-7-.02 STANDARDS

- (1) All sterile products shall be prepared in compliance with applicable USP standards for pharmaceutical compounding.
- (2) The Board of Pharmacy, upon a showing of good cause and in the best interest of the public health, safety and welfare, may waive the requirements of any applicable portion of USP standards.
 - (a) All waiver requests submitted pursuant to this part shall be submitted in writing.
 - (b) The Board of Pharmacy may authorize the Executive Director to exercise some, or all, of its waiver authority under this part.
- (3) Noncompliance by a licensee with applicable standards and guidelines, or any other violation of the provisions of this rule shall be considered unprofessional conduct within the meaning of T.C.A. 63-10-305 and a violation of a duly promulgated rule of the Board of Pharmacy.
- (4) Any licensed pharmacy which compounds sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of high risk or batch sterile products, as defined by USP standards, compounded and dispensed during the previous quarterly period and any other information as required by USP standards.
 - (a) Quarterly reports submitted pursuant to this paragraph shall be submitted by the 15th day of the month following the end of each calendar quarter.
 - (b) In any calendar year where any one of the above dates fall on a weekend or official state holiday, all quarterly reports due on that date shall be submitted on the following business day.

- (c) The format for reports submitted pursuant to this paragraph shall be determined by the Board of Pharmacy through policy and made available to the public on the Board of Pharmacy's website.
- (5) Any licensed pharmacy which compounds and dispenses sterile products shall provide at a minimum upon request of the Board of Pharmacy the following information for any sterile drug product compounded, dispensed, traded, sold, or otherwise distributed:
- (a) name, strength, and dosage form;
 - (b) quantity compounded, dispensed, traded, sold, or otherwise distributed during the preceding quarterly period;
 - (c) all components and an accurate statement of the weight or measure of each component;
 - (d) the beyond-use date;
 - (e) storage requirements;
 - (f) labels and labeling with appropriate beyond-use date and instructions for storage and use.
- (6) Any licensed pharmacy which compounds and dispenses sterile products must ensure that the following information is on file at the practice site and readily accessible for sterile products:
- (a) documentation of the name and strength of all drug products compounded over the past two (2) years;
 - (b) the sources and lot numbers of the components used in those drug products;
 - (c) the total number of dosage units compounded over the past two (2) years;
 - (d) the name of the person who prepared the drug product;
 - (e) the name of the pharmacist who approved the drug product;
 - (f) the name of the practitioner or the name of the patient or healthcare entity who received the compounded drug product;
 - (g) the results of any sampling, testing or other quantitative evaluation conducted for the purposes of quality control for any sterile compounded products, as defined by chapter 1140-01, compounded over the past two (2) years.

~~1140-07-.03 1140-7-.02~~ **PERSONNEL.**

- (1) The pharmacist in charge or pharmacist designee shall be responsible for, at a minimum, the following:
- (a) Procurement, storage, compounding, labeling, repackaging, dispensing, and distribution of all prescription drugs and devices and related materials necessary in compounding and dispensing sterile products;
 - (b) Establishment of policies and procedures for the compounding and dispensing of sterile products;

- (c) Documentation of competency in aseptic techniques of all pharmacists, pharmacy interns and pharmacy technicians. The aseptic technique of each person compounding and dispensing sterile products shall be observed and evaluated as satisfactory during orientation and training and at least on an annual basis or whenever unacceptable techniques are observed or detected;
 - (d) Establishment of a quality assurance program;
 - (e) Reviewing and updating annually all policies and procedures; and
 - (f) Provision of sterile products on a twenty four (24) hour a day basis.
- (2) All pharmacists, pharmacy interns and pharmacy technicians as defined in 1140-2-.02 responsible for compounding or dispensing sterile products shall:
- (a) Obtain practical and/or academic training in the compounding and dispensing of sterile products;
 - (b) Complete annual continuing education related to sterile product compounding and dispensing and utilization; and
 - (c) Maintain, in the pharmacy practice site, documentation of completion of the required training and continuing education.
 - (d) Use proper aseptic technique in all sterile product compounding as defined by the pharmacy practice site's policies and procedures.
- (3) A pharmacist shall be available to respond to patients' and other health care practitioners' information needs on a twenty four (24) hour a day basis.
- (4) The pharmacist in charge shall be assisted by such additional pharmacists, pharmacy interns, pharmacy technicians as defined by 1140-2-.02 and supportive personnel necessary to operate the pharmacy practice site competently and safely and to provide services in a timely and appropriate manner.
- (5) All pharmacists, pharmacy interns and pharmacy technicians must be qualified through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such pharmacists, interns and technicians will be assigned to use to compound and dispense sterile products.
- (6) A written record of initial and subsequent training and competency evaluations shall be maintained in the pharmacy practice site and contain the following information:
- (a) Name of the person receiving the training or evaluation;
 - (b) Date(s) of the training or evaluation;
 - (c) General description of the topics covered; and
 - (d) Signature of the person receiving the training or evaluation and the pharmacist in charge or pharmacist designee of the pharmacist in charge.

Authority: T.C.A. § 63-10-404(4),(5),(8),(11),(14),(16),(26),(27),(29),(30), §63-10-504(b)(1),(2). **Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

(1) Any facility that compounds sterile products shall comply with applicable USP standards.

Board of Pharmacy paragraph:

(1) Area, Equipment and Materials.

- (a) 1. The sterile product compounding area shall be enclosed from other pharmacy practice site operations in order to minimize the potential for sterile product contamination.
2. This area shall be designed as a limited access area to avoid unnecessary traffic and airflow disturbances.
3. The enclosure of the sterile product compounding area may be achieved through the utilization of partitions, plastic curtains, or similar washable solid surface dividers.
4. Entrances to the sterile product compounding area must contribute to the enclosure.
5. Materials utilized to define the enclosure must extend from the floor to a minimum of the top of the hood.
6. All surfaces of the sterile product compounding area shall be washable, non carpeted, and low particulate generating.
7. No new construction or remodeling will be approved that is not either:
- (i) Fully enclosed as noted in paragraphs (3), (4) and (5) above; or
- (ii) Has documented engineering studies validating that air flow in a partially opened design creates an atmosphere that is equal to a fully enclosed design.
- (b) For hand washing a sink with hot and cold running water shall be located in or adjacent to the area where sterile products are compounded.
- (c) There shall be appropriate refrigeration for storing supplies and sterile products requiring refrigeration after being prepared and before being dispensed or administered to patients.
1. Documentation of refrigeration integrity shall be maintained in accordance with the pharmacy practice site's policies and procedures.
- (d) The storage of prescription drugs and devices and related materials shall be under appropriate conditions (e.g., controlled temperature, well lighted, dry, clean, secure, and well ventilated).
1. Prescription drugs and devices and related materials shall not be stored in the sterile product compounding area in shipping containers (e.g., corrugated cardboard or other high particulate producing containers).
2. After removal from shipping containers, unit packaging will be acceptable for storage in the sterile product compounding area.

- ~~(e) All sterile product compounding must be performed within a Class 100 laminar flow hood, biologic safety cabinet (Class II, Type A) or within a Class 100 clean room.~~
- ~~(f) Laminar flow hoods, biologic safety cabinets (Class II, Type A) and Class 100 clean rooms shall be certified according to current federal standards for operational efficiency at least semi-annually.~~
- ~~(g) The laminar flow hood, biologic safety cabinet (Class II, Type A) or Class 100 clean room shall be kept running continuously; however, if the hood is turned off, the hood shall be functioning at least thirty (30) minutes before being used to compound sterile products, or according to recommendations of the manufacturer to achieve appropriate air velocity and a complete cleaning of the inside works before being used to compound sterile products.~~
- ~~(h) The sterile product compounding area shall be adequately ventilated so as not to interfere with laminar flow hood conditions and be used only for the compounding of sterile products.~~
- ~~(i) Prefilters in laminar flow hoods shall be changed at least quarterly and a written record of such change shall be maintained.~~
- ~~(j) The storage of prescription drugs, devices and related materials outside of the pharmacy shall be supervised and approved by the pharmacist in charge and inspected monthly to ensure that the products' safe storage is being maintained. These inspections shall be in accordance with rule 1140-4-18. *Authority: T.C.A. § 63-10-404(4),(8),(14), § 63-10-504(b)(1),(2). Administrative History: Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*~~

~~1140-07-.05~~ 1140-7-.04 **POLICY AND PROCEDURE MANUAL.**

- (1) A policy and procedure manual related to sterile product compounding shall be available for inspection at the pharmacy practice site. The manual shall include policies and procedures for sterile compounding pursuant to USP standards, and shall, at a minimum, include:
 - (a) security;
 - (b) equipment;
 - (c) sanitation;
 - (d) reference materials;
 - (e) prescription drug and device and related material storage;
 - (f) prescription drug and device and related material compounding and dispensing;
 - (g) prescription drug and device and related material labeling and relabeling;
 - (h) prescription drug and device and related material destruction and returns;
 - (i) dispensing of sterile products;
 - (j) record keeping;
 - (k) quality assurance;
 - (l) quality control;
 - (m) duties for pharmacist(s), pharmacy intern(s), pharmacy technician(s) and supportive personnel;
 - (n) public safety relative to harmful sterile products, including the active notification of patients if they may be affected by a product found to have a defect or an out-of-specification result including any recall policy and procedures;
 - (o) attire; and
 - (p) pharmacist, pharmacy intern, and pharmacy technician training.
 - (q) compliance with all applicable USP standards; and

- (r) response to adverse events, outbreaks, and other public health threats associated with products compounded, dispensed, manufactured, propagated, distributed, or otherwise processed at the facility, including procedures for the rapid compilation and dissemination of records to appropriate authorities.
- (2) Any licensed facility which engages in sterile compounding shall conduct an annual review of its policy and procedure manual, and shall update its policy and procedure manual as necessary.
- (3) Failure by any licensee or registrant to comply with its policy and procedure manual, or any part of this rule shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: T.C.A. § 63-10-404(4),(8),(14),(26),(29),(30), § 63-10-504(b)(1),(2). **Administrative History:** Original rule filed October 1, 1987; effective November 15, 1987. Amendment filed November 16, 1992; effective January 8, 1993. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

~~1140-07-.06~~ ~~1140-7-.05~~ **LABELING.**

- (1) At the time of dispensing of the sterile product, the dispensing container must bear a label which contains the following information:
 - (a) patient's name (if for outpatient use) or healthcare entity name;
 - (b) prescriber (s) name (if for outpatient use);
 - (c) pharmacy practice site name, address, and phone number (if for outpatient use);
 - (d) identification of the pharmacist who compounded the sterile product;
 - (e) when applicable, identification of the pharmacy intern or pharmacy technician who assisted in the compounding of the sterile product;
 - (f) name and amount of drug added;
 - (g) expiration date and, when applicable, expiration time, Beyond Use Dating (BUD);
 - (h) date of compounding;
 - (i) appropriate auxiliary label(s); and
 - (j) directions for use (if for outpatient), if applicable.
- (2) Original medical or prescription orders for sterile products shall comply with applicable state and federal laws and regulations.

Authority: T.C.A. §63-10-404(11),(14),(19),(26),(28),(29),(30),(32),(34), §63-10-504(b(1),(2). **Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

~~1140-07-.07~~ ~~1140-7-.06~~ **HAZARDOUS PRODUCTS.**

- (1) Physical Requirements.
 - (a) If the pharmacy practice site is engaged in the compounding of hazardous sterile products, a suitable facility to prepare such products and minimize the risk associated with such products shall be provided.
 - (b) Such pharmacy practice site shall be designed and equipped for storage and have a procedure for disposal of materials containing hazardous residues in accordance with state and federal laws.

- (1) A dedicated Class II, Type A contained vertical flow biohazard cabinet is the minimally acceptable compounding site for the routine compounding of hazardous sterile products.
- (2) Hazardous sterile products shall be segregated within the pharmacy practice site and storage areas so identified.
- (2) Dispensing.
 - (a) Prepared doses of hazardous sterile products for patients shall be placed in an appropriate outer wrap to minimize the risk exposure in case of accidental rupture of the primary container.
 - (b) Reasonable effort shall be made to assure that all hazardous sterile product primary containers and waste are removed from the site of use and disposed of as hazardous waste in accordance with applicable state and federal laws.
- (3) Training.
 - (a) As part of the training for all pharmacists, pharmacy interns and pharmacy technicians involved in compounding of hazardous sterile products, an annual certification must be made by each pharmacist, pharmacy intern and pharmacy technician and the pharmacist in charge that each has read and understands the latest editions of:
 1. Work Practice Guidelines for Personnel Dealing with Cytotoxic (Antineoplastic) Drugs (Occupational); and
 2. The American Society of Health-System Pharmacists (ASHP) technical assistance bulletin on handling cytotoxic and hazardous substances.
- (4) Hazardous sterile products dispensed shall bear a distinctive warning label with an appropriate caution statement thereon.
- (5) Gloving and gowning shall be required in the compounding of hazardous sterile products. Gloves should be rinsed frequently with a sanitizing agent (e.g., seventy percent (70%) isopropyl alcohol) and shall be changed when the integrity of the gloves is compromised.
- (6) In the compounding of hazardous sterile products, a protective disposable gown made of lint-free low permeability fabric with a closed front, long sleeves and elastic or knit closed cuffs with cuffs tucked under the gloves shall be worn. Gowns and gloves used in the compounding of hazardous sterile products shall not be worn outside the sterile product compounding area.

Authority: T.C.A. § 63-10-404(4),(11),(26),(27),(28),(29),(30), § 63-10-504(b)(1),(2). **Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-07-.08 1140-7-.07 **ATTIRE.**

- (1) All pharmacists, pharmacy interns and pharmacy technicians shall wear applicable outer garments and shall use applicable respiratory precautions as set out in USP 797. ~~clean garments that generate low levels of particulate. Concerning clothing worn in a sterile product compounding area with a laminar flow hood or biologic safety cabinet (Class II, Type A), one (1) of the following must apply:~~
 - (a) ~~Upon entering the sterile product compounding area, pharmacists, pharmacy interns and pharmacy technicians shall don an outer garment that generates a low level of particulate (e.g.,~~

clean laboratory jacket, disposable gown) before compounding sterile products. Upon leaving the sterile product compounding area, this outer garment shall be disposed of or left at the entrance of the sterile product compounding area and donned when re-entering the area.

- (b) ~~If scrubs or site specific clothing are donned for work in the sterile product compounding area, a laboratory jacket or outer covering shall be worn while outside the sterile product compounding area in order to protect the scrubs or site specific clothing from cross contamination. Upon entering the sterile product compounding area the lab jacket or outer covering shall be removed before compounding sterile products.~~
- (2) ~~All pharmacists, pharmacy interns and pharmacy technicians with respiratory conditions that may result in contamination of sterile products shall wear a mask.~~
- (3) ~~For the compounding of sterile products prior to receipt of specific medical or prescription orders and when the anticipated dispensing time may be greater than twenty eight (28) hours after preparation; clean, low particulate outer garments and gloves shall be required. Hair cover and a mask shall be required, unless a biologic safety cabinet (Class II, Type A) is utilized.~~
- (4) ~~If utilizing a Class 100 clean room without a laminar flow hood, the attire shall include a jumpsuit or surgical scrubs and head coverings that generate low levels of particulate, mask, shoe covers, and gloves.~~
- (5) ~~Attire specific to the compounding of hazardous sterile products is explained in rule 1140-7-06.~~

Authority: T.C.A. § 63-10-404(4),(26),(29),(30), § 63-10-504(b)(1),(2). **Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

~~1140-07-09~~ ~~1140-7-08~~ **QUALITY ASSURANCE.**

- (1) There shall be a documented, ongoing quality assurance program that monitors process validation; pharmacist(s), pharmacy intern(s), and pharmacy technician(s) performance; equipment; and environment.
- (2) The program shall be designed to assure that the pharmacy practice site is capable of consistently compounding quality sterile products.
- (3) All quality assurance programs shall follow applicable USP standards.
- (4) As part of its quality assurance program, any licensed facility which engages in sterile compounding shall perform a gap analysis pursuant to guidelines adopted by the Board of Pharmacy. Any exceptions or serious deficiencies noted in this analysis shall be reported to the Board of Pharmacy.
- (5) Failure by any licensee or registrant to comply with its quality assurance program shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: T. C.A. § 63-10-404(26),(28),(29),(30), § 63-10-504(b)(1),(2). **Administrative History:** Original chapter filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

(Rule 1140-9-.05, continued)

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-9
MANUFACTURERS AND WHOLESALERS/DISTRIBUTORS**

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1140-~~9~~-01 MANUFACTURER AND WHOLESALER/DISTRIBUTOR LICENSING.

- (1) Every manufacturer or wholesaler/distributor, before engaging in the manufacture, sale or distribution of prescription drugs and prescription devices in this state, must be licensed by the Board in accordance with this chapter.
- (2) An applicant with physical facilities in this state must obtain and display prominently a separate license for each principal place of business where the applicant manufactures or distributes prescription drugs and prescription devices.
- (3) The requirement of a license shall not apply to the following types of distributions:
 - (a) Intracompany sales;
 - (b) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
 - (c) The sale, purchase or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
 - (d) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control; for purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership of stock, voting rights, by contract or otherwise;
 - (e) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons; for purpose of this subparagraph, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy practice site to alleviate a temporary shortage.
 - (f) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase or trade a prescription drug, or the dispensing of a prescription drug pursuant to a medical or prescription order;

- (g) The distribution of prescription drug samples by manufacturers' representatives; or
- (h) The sale, purchase, or trade of blood and blood components intended for transfusion.
 - 1. The sale, purchase, or trade of a prescription drug, or an offer to sell, purchase or trade of a prescription drug by a pharmacy practice site to another pharmacy practice site or to authorized prescribing practitioners, except that the total gross dollar volume of such transfers shall not exceed five percent (5%) of the total medical and prescription orders sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period.

Authority: T.C.A. § 63-10-404(2),(8),(14),(18),(37), § 63-10-504(b)(1), § 63-10-506(f). Administrative History: Original rule filed January 7, 1992; effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-09-02 MINIMUM INFORMATION REQUIRED.

- (1) The board shall require the following minimum information from each manufacturer or wholesaler/distributor applying for a license or any renewal of such license:
 - (a) The name, full business address, and telephone number of the manufacturer or wholesaler/distributor;
 - (b) All trade or business names used by the manufacturer or wholesaler/distributor;
 - (c) Addresses, telephone numbers, and the names of contact persons for all facilities used by the manufacturer or wholesaler/distributor for storage, handling, and distribution;
 - (d) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
 - (e) The name(s) of the owner and/or operator of the manufacturer or wholesaler/distributor, including:
 - 1. If a person, the name of the person;
 - 2. If a partnership, the name of each partner, and the name of the partnership;
 - 3. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;
 - 4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and
 - 5. DEA registration number if applicable; and
 - 6. The results of a criminal background check for the owner or manager of the facility seeking licensure, submitted directly to the Board of Pharmacy by the vendor identified in the Board of Pharmacy's licensure application materials.
- (2) Applicants seeking to register as manufacturers shall provide the following materials to the Board of Pharmacy:
 - (a) Proof of registration with the Food and Drug Administration as a manufacturer and the most current inspection by that agency, or correspondence or other written proof

from the Food and Drug Administration which states that registration with that agency is unnecessary.

(b) The name and contact information of the owner, the owner's agent, or another such individual employed at or contracted by the applicant that can be reached at any time by the Board of Pharmacy, the Department of Health or any agents thereof in the event of a potential or actual public health threat related to the sterility or potency of any drug or biologic product manufactured, wholesaled or distributed by the applicant.

(3) Applicants seeking to register as sterile manufacturers shall provide the following materials to the Board of Pharmacy:

(a) Upon request by the Board of Pharmacy or the executive director, a list of sterile products currently being manufactured, wholesaled and distributed;

(b) The name and contact information for any laboratory, corporation, or other organization that may perform sterility and potency testing, or similar procedures for the purposes of quality assurance on any drug or biologic product produced by the applicant;

(4) Changes in any information in paragraphs (1), (2), or (3) of this rule shall be submitted in writing to the Board of Pharmacy immediately.

Authority: T.C.A. § 63-10-404(2),(18),(37), § 63-10-504(b)(1), § 63-10-506(f). Administrative History: Original rule filed January 7, 1992; effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-9-.03 MINIMUM QUALIFICATIONS.

(1) The board shall consider, at a minimum, the following factors in reviewing an application for a license as a manufacturer or wholesaler~~distributor~~:

(a) Any convictions of the applicant under any federal, state, or local laws relating to drug samples or distribution of controlled substances;

(b) Any felony convictions of the applicant under federal, state, or local laws;

(c) The applicant's past experience in the manufacturing or distribution of prescription drugs and prescription devices, including controlled substances;

(d) The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distribution;

(e) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances, prescription drugs and prescription devices;

(f) Compliance with licensing requirements under previously granted licenses, if any;

(g) Compliance with requirements to maintain and/or make available to the board or to federal, state, or local law enforcement officials those records required federal, state or local laws; and

(h) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

- (2) The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

Authority: T.C.A. § 63-10-404(2),(6),(8),(14),(18),(37), § 63-10-504(b)(1). **Administrative History:** Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1999, effective July 25, 1998.

1140-9-.04 PERSONNEL.

The board shall require that personnel employed by a manufacturer or wholesaler/distributor have appropriate education and/or experience to assume positions of responsibility for compliance with board requirements.

Authority: T.C.A. § 63-10-404(2),(18),(37), § 63-10-504(b)(1). **Administrative History:** Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-09-.05 MINIMUM REQUIREMENTS FOR GENERAL OPERATION.

The following shall be the minimum requirements for the storage and handling of prescription drugs and prescription devices and for the establishment and maintenance of prescription drug and prescription device distribution records by manufacturers and wholesalers/distributors:

- (1) Facilities. All facilities at which prescription drugs and prescription devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:
- (a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (c) Have a quarantine area for storage of prescription drugs and prescription devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
 - (d) Be maintained in a clean and orderly condition, and
 - (e) Be free from infestation by insects, rodents, birds, or vermin of any kind.
- (2) Security.
- (a) All facilities shall be secure from unauthorized entry.
 - 1. Access from outside the premises shall be kept to a minimum and be well-controlled.
 - 2. The outside perimeter of the premises shall be well-lighted.
 - 3. Entry into areas where prescription drugs and prescription devices are held shall be limited to authorized personnel.
 - (b) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

- (3) Storage. All prescription drugs and prescription devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs and devices, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).
- (a) If no storage requirements are established for a prescription drug or prescription device it may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that identity, strength, quality, and purity are not adversely affected.
 - (b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs and prescription devices.
 - (c) The record keeping requirements in paragraph (6) of this section shall be followed for all prescription drugs and prescription devices.
- (4) Examination of materials.
- (a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
 - (c) The record keeping requirements in paragraph (6) of this section shall be followed for all incoming and outgoing prescription drugs.
- (5) Returned, damaged, and outdated prescription drugs and prescription devices.
- (a) Prescription drugs and prescription devices that are outside, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs and prescription devices until destroyed or returned.
 - (b) Any prescription drugs and prescription devices whose immediate or sealed outer or sealed secondary containers have been opened or used shall be quarantined and physically separated from other prescription drugs and prescription devices until either destroyed or returned.
 - (c) If the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, then the prescription drug or prescription device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the prescription drug or prescription device meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, the manufacturer or wholesaler/distributor shall consider, among other things, the conditions under which the prescription drug or prescription device has been held, stored or shipped before or during return and the condition of the prescription drug or device or related material and its container, carton, or labeling, as a result of storage or shipping.

(d) The record keeping requirements in paragraph (6) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and prescription devices.

(6) Record keeping.

(a) Manufacturers and wholesalers/distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription devices. These records shall include the following information:

1. The source of the prescription drugs and prescription devices including the name and principal address of the seller or transferor, and the address of the location from which the prescription drugs and prescription devices were shipped;
2. The identity and quantity of the prescription drugs and prescription devices received and distributed or disposed of; and
3. The dates of receipt and distribution or other disposition of the prescription drugs and prescription devices.

(b) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the prescription drugs and prescription devices.

(c) Records described in this paragraph that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(7) Written policies and procedures. Manufacturers and wholesalers/distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs and prescription devices; including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Manufacturers and wholesalers/distributors shall include in written policies and procedures the following:

(a) A procedure whereby the older approved stock of a prescription drug or prescription device is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs and prescription devices. Such procedures shall be adequate to respond to recalls and withdrawals due to:

1. Any action initiated at the request of the United States Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board;
2. Any voluntary action by the manufacturer or wholesaler/distributor to remove defective or potentially defective prescription drugs and prescription devices from the market; or

3. Any action undertaken to promote public health and safety by replacing of an existing product with an improved product or new package design.
 - (c) A procedure to ensure that manufacturers and wholesalers/distributors prepare for, protect against, and respond to any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
 - (d) A procedure to ensure that any outdated prescription drugs and prescription devices shall be segregated from other prescription drugs and prescription devices and either returned to the manufacturer or wholesaler/distributor or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs and prescription devices. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs and prescription devices.
- (8) Responsible persons. Manufacturers and wholesalers/distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of distribution, storage, and handling, including a description of such persons' duties and a summary of such persons' qualifications.
- (9) Compliance with federal, state, and local law. Manufacturers and wholesalers/distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
 - (a) Manufacturers and wholesalers/distributors shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect premises and delivery vehicles, and to audit records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.
 - (b) Manufacturers and wholesalers/distributors that handle controlled substances shall register with the board and with the United States Drug Enforcement Administration (DEA) and shall comply with applicable state, local and DEA regulations.
- (10) Salvaging and reprocessing. Manufacturers and wholesalers/distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to salvaging or reprocessing of prescription drugs and prescription devices.

Authority: T.C.A. § 63-10-404(8),(18),(33),(37), § 63-10-504(b)(1). **Administrative History:** Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-09 -.06 MINIMUM REQUIREMENTS FOR STERILE PRODUCT OPERATION

- (1) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter that also holds an active sterile compounding registration from the Board of Pharmacy and that holds a license or registration from the Federal Food and Drug Administration, shall comply with all applicable federal laws, regulations, and guidelines including, but not limited to:
 - (a) FDA Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs 21 CFR 210;
 - (b) FDA Current Good Manufacturing Practice for Finished Pharmaceuticals 21 CFR 211;
 - (c) DEA regulations relating to controlled substances 21 CFR 1300-99.
- (2) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy and who does not hold a license or

registration from the federal Food and Drug Administration shall comply with all applicable USP standards.

- (3) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy shall comply with all other applicable Board of Pharmacy rules and all other applicable laws of this State.
- (4) The Board of Pharmacy may waive any applicable USP standards upon a showing by the applicant that good cause exists and that a waiver would better promote public health, safety, and welfare.

Authority: T.C.A. § 63-10-404(8),(18),(33),(37), § 63-10-504(b)(1). Administrative History: Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.